

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

IN RE NAMENDA DIRECT PURCHASE  ANTITRUST LITIGATION	No. 15-cv-7488-CM  FILED UNDER SEAL
---	---

**DEFENDANTS' CORRECTED STATEMENT OF UNDISPUTED MATERIAL FACTS  
IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

**TABLE OF CONTENTS**

	<u>Page</u>
<b>BACKGROUND</b>	<b>1</b>
A. Alzheimer’s Disease .....	1
B. The ‘703 Patent .....	2
C. Patent Term Extension .....	8
D. FDA Approval and Launch of Namenda IR .....	13
E. FDA Approval and Launch of Namenda XR .....	14
F. Forest’s Marketing of Namenda .....	15
G. Pediatric Exclusivity .....	17
H. Lexapro .....	19
I. Teflaro/Ceftaroline .....	20
<b>II. Generic Settlements: No Reverse Payments .....</b>	<b>21</b>
A. Terms of the Settlement Agreements with the Generic Defendants .....	21
B. Forest’s Search for a Secondary Supplier of Ceftaroline .....	40
C. The Ceftaroline Supply Agreement with Orchid .....	44
D. The Orchid Settlement Agreement .....	47
E. The Lexapro Agreement with Alphapharm .....	50
F. The Deficit Reduction Act of 2005 and the Issue of “Best Price” Liability .....	53
G. Projected Benefits of Forest Amending the Lexapro Agreement .....	59
i. Forest’s Projected Savings from Shifting Manufacturing of the Lexapro Authorized Generic to Mylan .....	61
ii. Forest’s Projected Earnings Under a Possible Lexapro Amendment with Mylan .....	66
H. The Lexapro Amendment with Mylan .....	73
I. Mylan’s Threatened Antitrust Suit .....	76
J. The Mylan Settlement Agreement .....	78
<b>III. Generic Settlements: No Causation .....</b>	<b>80</b>
A. The Namenda IR Patent Litigation Against Fifteen Generic Defendants .....	80
B. The Namenda Patent Litigation Claim-Construction Ruling .....	81
C. Settlements and Dismissals .....	84
D. The Mylan Litigation .....	87
i. Infringement .....	87
ii. Anticipation .....	90
iii. Obviousness .....	91
iv. Enablement .....	93
E. No Evidence of Any Generics Planning an “At-Risk” Launch .....	95
F. No Evidence that Forest Considered Launching a Namenda IR Authorized Generic in the 2010-2012 Timeframe .....	96
G. No Evidence an Earlier Entry Date Was Considered for Settlements .....	97
H. There is No Evidence that Generics Could Have Entered in 2012 .....	98
<b>IV. Generic Settlements: No Conspiracy .....</b>	<b>100</b>
A. The Namenda IR Patent Settlements Contained Generic Entry Early	

	Acceleration Clauses.....	100
B.	Generic Entry Early Acceleration Clauses Provided the Same Protection that Generics Manufacturer Were Entitled to Under Hatch-Waxman.....	101
C.	No Evidence of a Conspiracy with or Between Generic Defendants .....	102
D.	Settlements were in Each Generic Defendant’s Individual Best Interest .....	104
E.	No Motive for Generic Defendants to Conspire .....	106
F.	The Generic Entry Early Acceleration Clauses Ensured Substantial Generic Entry.....	107
<b>V.</b>	<b>Hard Switch: No Antitrust Injury.....</b>	<b>108</b>
A.	The June 2013 Launch of Namenda XR.....	108
B.	Favorable Formulary Placement for Namenda XR .....	110
C.	Namenda XR Priced at a Discount to Namenda IR .....	114
D.	Projected Conversion Rates .....	115
E.	Actual Conversion Rates.....	120
F.	The February 2014 Planned-Withdrawal Announcement .....	126
G.	The Continued-Availability Announcement in June 2014 .....	128
H.	The Standstill Agreement .....	129
I.	The December 2014 Injunction .....	129
J.	The January 2015 Continued-Availability Announcement .....	131
K.	Subsequent Announcements and the Settlement with the New York Attorney General.....	133
L.	Entry of Generic Namenda IR in July and October of 2015.....	135
M.	No Way to Identify if Any Patients Switched Because of the February 2014 Announcement.....	139
N.	No Way to Know if Patients Switched to Namenda XR for Other Reasons, Including Lower Price, Formulary Placement, or Product Convenience .....	141
O.	No Way to Know How Many People Switched Back to Generic Namenda IR From Namenda XR.....	144
P.	The Injunction Undid Any Purported Harm of the February 2014 Announcement.....	147
Q.	The January 2015 Continued-Availability Announcement Undid Any Purported Harm of the February 2014 Announcement .....	148
R.	The New York Attorney General Confirmed the Effect of the Announcement was Undone By Forest’s Compliance with the Injunction .....	149

## BACKGROUND

### A. Alzheimer's Disease

1. Alzheimer's is a progressive, irreversible, and degenerative disease of the brain for which there is no cure.

Defendants' Evidence: Ex. 1, FRX-AT-01779611, October 19, 2014 Declaration of Steven H. Ferris ("Ferris Decl."), ¶ 11.

Plaintiffs' Admissions: First Amended Class Action Complaint (Oct. 13, 2015) ("Am. Compl."), Case No.: 15-cv-7488, ECF No. 26, ¶ 91.

2. All current therapies treat the symptoms of Alzheimer's but do not reverse its effects.

Defendants' Evidence: Ex. 1, Ferris Decl. ¶ 13.

Plaintiffs' Admissions: Am. Compl. ¶ 92.

3. Alzheimer's affects over five million Americans and is the sixth leading cause of death in the United States.

Defendants' Evidence: Ex. 1, Ferris Decl. ¶ 11.

Plaintiffs' Admissions: Am. Compl. ¶ 91.

4. As the population continues to live longer, the number of Americans living with Alzheimer's is expected to triple by 2050.

Plaintiffs' Admissions: Am Compl. ¶ 91.

5. Early symptoms of Alzheimer's include short-term memory loss, difficulty performing familiar tasks, disorientation, trouble with language, and mood swings. Patients also

develop neuropsychiatric problems, including apathy, depression, agitation and delusions. As the disease progresses, patients may be unable to walk or to recognize and communicate with family members and friends.

Defendants' Evidence: Ex. 1, Ferris Decl. ¶ 11.

Plaintiffs' Admissions: Am. Compl. ¶ 91.

6. As the disease worsens, patients are unable to function independently, becoming increasingly dependent on caregivers.

Defendants' Evidence: Ex. 1, Ferris Decl. ¶ 11.

Plaintiffs' Admissions: Am. Compl. ¶ 91.

7. In the final stages of the disease, patients require skilled nursing and intensive support care.

Defendants' Evidence: Ex. 1, Ferris Decl. ¶ 11.

#### **B. The '703 Patent**

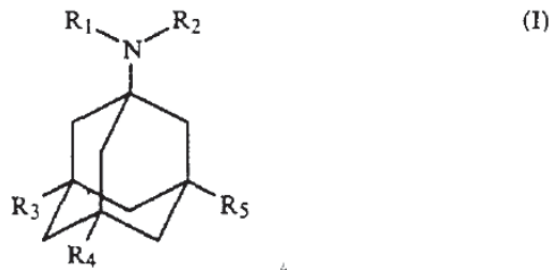
8. U.S. Patent No. 5,061,703 ("703 Patent") issued on October 29, 1991 and is entitled "Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia."

Public Documents: Ex. 2, U.S. Patent No. 5,061,703.

Plaintiffs' Admissions: Ex. 3, Sept. 15, 2017 Expert Report of George W. Johnston ("Johnston Rep.") ¶ 29.

10. When issued, claim 1 of the '703 patent covered:

1. A method for the prevention or treatment of cerebral ischemia comprising the step of administering, to a patient in need thereof, an effective amount of an adamantane derivative of the general formula



wherein

$R_1$  and  $R_2$  are identical or different and represent hydrogen or a straight or branched alkyl group of 1 to 6 C atoms or, in conjunction with N, a heterocyclic group with 5 or 6 ring C atoms;

wherein

$R_3$  and  $R_4$  are identical or different, being selected from hydrogen, a straight or branched alkyl group of 1 to 6 C atoms, a cycloalkyl group with 5 or 6 C atoms, and phenyl;

wherein

$R_5$  is hydrogen or a straight or branched  $C_1$ - $C_6$  alkyl group,  
or a pharmaceutically-acceptable salt thereof.

Public Documents: Ex. 2, '703 Patent.

Plaintiffs' Admissions: Ex. 3, Johnston Rep. ¶ 36.

11. The chemical formula in claim 1 covers memantine.

Public Documents: Ex. 2, '703 Patent.

12. The '703 patent was assigned to Merz + Co. GmbH & Co., which, in turn, licensed the '703 patent to Forest.

Public Documents: Ex. 2, ‘703 Patent.

Defendants’ Evidence: Ex. 4, FRX-AT-01710620, Merz-Forest Supply and Cooperation Agreement, dated June 28, 2000; Ex. 5, McKelvie Rep. ¶¶ 45, 51.

Plaintiffs’ Admissions: Am. Compl. ¶ 93; *In re Namenda Direct Purchaser Antitrust Litigation*, Statement of Material Facts ISO DPPs’ Motion for SJ Count One (S.D.N.Y. Feb. 16, 2017) (“DPPs’ Statement of Material Facts ISO Count One”), 15-cv-7488, ECF No. 137, ¶ 3; *In re Namenda Direct Purchaser Antitrust Litigation, Statement of Material Facts ISO DPPs’ Motion for SJ Count Three* (S.D.N.Y. Feb. 16, 2017) (“DPPs’ Statement of Material Facts ISO Count Three”), 15-cv-7488, ECF No. 141, ¶ 3.

13. On August 18, 2004, Forest filed for reexamination request for the ‘703 patent.

Public Documents: Ex. 7, Application No. 90/007,176, (“‘703 Reexamination File History”), available at <https://portal.uspto.gov/pair/PublicPair>

Defendants’ Evidence: Ex. 5, McKelvie Rep. ¶ 47.

Plaintiffs’ Admissions: Ex. 3, Johnston Rep. ¶ 41.

14. With its application, Forest disclosed several articles for the U.S. Patent and Trademark Office (“PTO”) to consider in deciding whether the claims were patentable, including:

- Japanese Patent Publication No. JP 58-4718
- Rote Liste, 63-008 (1986)(“Rote Liste”)
- Marcea et al., *Therapiewoche*, 38:3097-3100 (1988) (“Marcea”)
- Ambrozi et al., *Pharmacopsychiatry*, 21:144-146 (1988) (“Ambrozi”)
- Fleischhacker et al., *Progress in Neuro-psychopharmacology and Biological Psychiatry*, 10:87-93 (1986) (“Fleischhacker”)

Forest stated in its reexamination application that those references raised a substantial new question of patentability regarding 35 U.S.C. § 102 (anticipation) and 35 U.S.C. § 103 (obviousness).

Public Documents: Ex. 7, ‘703 Reexamination File History at 4-5, 11.

Defendants’ Evidence: Ex.5, McKelvie Rep. ¶ 48.

Plaintiffs’ Admissions: *See also*, Ex. 3, Johnston Rep. ¶ 42.

15. The PTO opened reexamination proceedings and, on March 10, 2005, issued an initial rejection of all the claims, finding them unpatentable, under 35 U.S.C. § 102 in view of Rote Liste, Marcea, Ambrozi, and Fleischhacker.

Public Documents: Ex. 7, ‘703 Reexamination File History at 65-67.

Plaintiffs’ Admissions: Ex. 3, Johnston Rep. ¶ 42.

16. In response, Forest argued that its claims were patentable notwithstanding the disclosure of the references the PTO cited.

Public Documents: Ex. 7, ‘703 Reexamination File History at 78-90.

17. Forest amended its claims to further distinguish them from the information disclosed in the references.

Public Documents: Ex. 7, ‘703 Reexamination File History at 73-78.

Plaintiffs’ Admissions: Ex. 3, Johnston Rep. ¶ 42, 45.

18. In response, the PTO withdrew the 35 U.S.C. § 102 anticipation rejection. The PTO issued a reexamination certificate on November 7, 2006. The reexamination certificate lists

Marcea, Ambrozi, Fleischhacker, Tempel, *Memantine in organic brain syndrome: Can disturbed social and self-care behaviors be improved?*, *Therapiewoche* 39:946-952 (1989) (“Tempel”), and Fünfgeld et al., *Psychopharmacology*, XVI<sup>th</sup> C.I.N.P. Congress, Munich, 27.23.08 (Aug. 15-18, 1988) (“Fünfgeld”) as references that the PTO considered during reexamination.

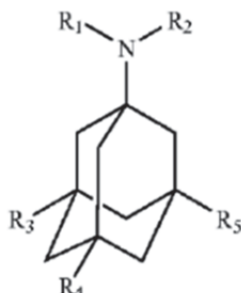
Public Documents: Ex. 7, ‘703 Reexamination File History at 118-19, 123-25 (Information Disclosure Statement submitted by Forest with examiner initials indicating consideration of Fünfgeld and Tempel), 174 (“[T]he four cited references [Rote Liste, Ambrozi, Marcea, and Fleischhacker] do not teach the oral administration of [memantine] is effective or the prevention or treatment of cerebral ischemia in a patient diagnosed with Alzheimer’s disease.”), 176-77 (listing as “References Cited” Fünfgeld, Tempel, Marcea, Ambrozi, and Fleischhacker).

Defendants’ Evidence: Ex. 5, McKelvie Rep. ¶ 48.

Plaintiffs’ Admissions: Ex. 3, Johnston Rep. ¶ 46.

19. As amended, reexamined claim 1 of the ‘703 patent reads:

I. A method for the prevention or treatment of cerebral ischemia comprising the step of *orally* administering, to a patient *diagnosed with Alzheimer's disease and in need thereof*, an effective amount of an adamantane derivative of the general formula



wherein

$R_1$  and  $R_2$  are identical or different and represent hydrogen or a straight or branched alkyl group of 1 to 6 C atoms or, in conjunction with N, a heterocyclic group with 5 or 6 ring C atoms;

wherein

$R_3$  and  $R_4$  are identical or different, being selected from hydrogen, a straight or branched alkyl group of 1 to 6 C atoms, a cycloalkyl group with 5 or 6 C atoms, and phenyl;

wherein

$R_5$  is hydrogen or a straight or branched  $C_1$ - $C_6$  alkyl group; *and*

wherein

*$R_1$ ,  $R_2$ ,  $R_3$ ,  $R_4$  and  $R_5$  do not all represent hydrogen simultaneously;*  
or a pharmaceutically-acceptable salt thereof.

The italicized portions of the amended claims were added during reexamination.

Public Documents: Ex. 7, '703 Patent Reexamination File.

Defendants' Evidence: Ex. 5, McKelvie Rep. ¶ 67.

Plaintiffs' Admissions: Ex. 3, Johnston Rep. Ex. G.

20. The '703 patent was originally set to expire on April 11, 2010.

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count One ¶ 9; DPPs' Statement of Material Facts ISO Count Three ¶ 9.

### **C. Patent Term Extension**

21. On July 10, 1989, Merz filed an IND No. 33,392 for memantine hydrochloride ("IND '392").

Defendants' Evidence: Ex. 182, Investigational New Drug Application (Jul. 10, 1989), FRX-AT-02177815 at 7819-7999.

22. IND '392 became effective on February 7, 1990 and remained active until January 13, 1994, when Merz requested inactivation of IND '392.

Defendants' Evidence: Ex. 183, Request for Inactivation of IND '392 (Jan. 13, 1994), FRX-AT-04248226 at 8302-8303.

23. Merz then requested reactivation on September 5, 1997, and IND '392 was reactivated shortly thereafter on October 9, 1997.

Defendants' Evidence: Ex. 183, Request for Reactivation of IND '392 (Sep. 5, 1997), FRX-AT-04248226 at 8305-8307.

24. Throughout 1989-1997, Merz conducted clinical studies outside the United States.

Defendants' Evidence: Ex. 184, Integrated Summary of Safety (Dec. 6, 2002) ("List of Completed Studies"), FRX-AT-02300444 at 0524-0548.

Undisputed Record Evidence: Ex. 166, Pretrial Order, *Forest Labs, Inc., et al. v. Cobalt Labs Inc., et al.*, 08-cv-00021, D.I. 468, (D. Del. Feb. 26, 2010), Ex. 11 ¶¶ 271-277 ["Pretrial Order"] (MNAT\_0000001 at 0166-0167).

25. Many studies were conducted overseas during the period when IND ‘392 was inactive, from January 1994 to September, 1997.

Defendants’ Evidence: Ex. 184, List of Completed Studies, FRX-AT-02300444 at 0524-0548

Undisputed Record Evidence: Ex. 166, Pretrial Order, Exhibit 11 ¶¶ 271-277

26. For example, MRZ 90001-9104 was conducted in France between October 1992 and July 1994, and MRZ 90001-9403 was conducted in Latvia from November 1994 to July 1995.

Defendants’ Evidence: Ex. 184, List of Completed Studies, at FRX-AT-02300525, 0528; Ex. 166, Pretrial Order, Exhibit 11 ¶¶ 271-277

27. Forest conducted numerous other non-US studies, including MRZ 90001-9105, conducted in France between June 1993 and June 1996, and MRZ 90001-9202, conducted in the United Kingdom from February 1994 to October 1998.

Defendants’ Evidence: Ex. 184, List of Completed Studies, at FRX-AT-02300528, 0526

28. On December 9, 2003, Forest submitted a Request for Extension of Patent Term under 35 U.S.C. § 156 for the ‘703 patent (the “PTE Application”) to the PTO.

Defendants’ Evidence: Ex. 183, Request for Extension of Patent Term (Dec. 9, 2003), FRX-AT-04248226.

29. In the PTE Application, pursuant to 37 C.F.R. § 1.740(a)(12), Forest provided a Statement as to the Length of Extension Claimed in accordance with 37 C.F.R. § 1.775.

Defendants’ Evidence: Ex. 183, Request for Extension of Patent Term (Dec. 9, 2003), FRX-AT-04248226.

30. In that statement, Forest listed the effective date of IND ‘392 as October 9, 1997 (the date on which FDA reactivated IND ‘392), and claimed an extension of 1,250 days (approximately 3.5 years).

Defendants’ Evidence: Ex. 183, Request for Extension of Patent Term (Dec. 9, 2003), FRX-AT-04248226 at 8238-8240

31. Forest included in its PTE Application a detailed chronology of IND ‘392 in the Submission Log.

Defendants’ Evidence: Ex. 183, Request for Extension of Patent Term (Dec. 9, 2003), FRX-AT-04248226 at 8309-58.

32. The Submission Log included information about Merz’s submissions under IND ‘392, including the date of each submission, a description of the significance of each submission, and a citation to the “Hard Copy #” of each submission (correlating to the information in the FDA’s files). Among the Submission Log entries were:

- July 10, 1989: “Initial IND Submission ...”
- April 29, 1991: “Annual Report (As per annual report, no US studies have begun yet)”
- January 20, 1993: “ ... IND was placed on clinical hold via phone on 3/4-Sept.-1992 ...”
- September 13, 1993: “ ... (As of Sept. 13, 1993, no studies were conducted during past year)”
- September 13, 1994: “ ... Request for inactivation of IND”
- August 29, 1997: “Reactivation of IND ...”

Defendants' Evidence: Ex. 183, Request for Extension of Patent Term (Dec. 9, 2003), FRX-AT-04248226 at 8309-58.

Plaintiffs Admissions: Ex. 3, Johnston Rep. ¶¶ 48-49.

33. On June 5, 2007, FDA published an entry in the Federal Register entitled “Determination of Regulatory Review Period for Purposes of Patent Extension: NAMENDA.”

Undisputed Record Evidence: Ex. 185, Federal Register Entry (Jun. 5, 2007), FRX-AT-02399093.

34. FDA noted that “[t]he applicant claims October 9, 1997, as the date the [IND] became effective. However, FDA records indicate that the original IND effective date was February 7, 1990, which was the date the original IND was removed from clinical hold.” FDA determined that the applicable regulatory review period for Namenda was 5,001 days: 4,699 days in the testing phase and 302 days in the approval phase.

Undisputed Record Evidence: Ex. 185, Federal Register Entry (Jun. 5, 2007), FRX-AT-02399093 at 9094.

35. According to Mylan, once the FDA decided that Forest’s regulatory review period began on February 7, 1990, rather than October 9, 1997, Forest’s statement in its application that there were zero days during which Forest did not exercise “due diligence” was incorrect. Rather, Mylan claimed, the number of days during which Forest was not diligent was 2801, i.e., between February 7, 1990 (original IND filing) and October 9, 1997 (IND reactivation). Mylan argued that violated 35 U.S.C. § 156, invalidating the ‘703 patent’s PTE, by not explaining this to the FDA.

Undisputed Record Evidence: Ex. 166, Pretrial Order, Exhibit 12, ¶¶ 218-19, 232, 289.

36. Mylan alleged in its pretrial order sections that neither Forest nor any other party petitioned the FDA to determine whether Forest exercised due diligence.

Undisputed Record Evidence: Ex. 166, Pretrial Order, Exhibit 12, ¶¶ 227-28.

37. On March 3, 2009, the PTO issued a Notice of Final Determination for the PTE Application.

Undisputed Record Evidence: Ex. 186, FRX-AT-04547818 (“Notice of Final Determination”).

38. The PTO subtracted 630 days from the 4,699 days of the testing phase, representing the portion of the regulatory review period that occurred prior to the issuance of the ‘703 patent on October 29, 1991. Applying the formula, “Period of Extension =  $\frac{1}{2}$  (Testing Phase) + Approval Phase,” the PTO calculated that the period of extension for the ‘703 patent was 2,336 days (6.4 years).

Undisputed Record Evidence: Ex. 186, Notice of Final Determination.

39. Because this number exceeds five years (1,825 days), the PTE was then limited to the maximum amount of PTE under 35 U.S.C. § 156(g)(6)(A): five years.

Undisputed Record Evidence: Ex. 186, Notice of Final Determination.

40. Accordingly, the PTO granted a five year PTE for the ‘703 patent.

Undisputed Record Evidence: Ex. 186, Notice of Final Determination at FRX-AT-04547818-7819.

41. On March 18, 2009, the PTO issued a Certificate Extending Patent Term Under 35 U.S.C. § 156 for the ‘703 patent, extending the term of the ‘703 patent from April 11, 2010 to April 11, 2015.

Undisputed Record Evidence: Ex. 187, FRX-AT-03879201.

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count One at 3, ¶ 10; DPPs' Statement of Material Facts ISO Count Three at 3, ¶ 12.

**D. FDA Approval and Launch of Namenda IR**

42. Memantine, “an N-methyl D-aspartate (NMDA) antagonist, is prescribed to treat moderate to severe Alzheimer’s disease.”

Public Document: National Institute of Health, *How is Alzheimer’s Disease Treated?*, 1 (May 18, 2017), <https://www.nia.nih.gov/health/how-alzheimers-disease-treated>.

Undisputed Record Evidence: Ex. 6, FRX-AT-01747338, Opinion, New York v. Actavis, Plc and Forest Laboratories, LLC, 14-Civ-7473 (S.D.N.Y. Dec. 1, 2014) (“Unredacted Sweet Op.”) ¶ 8.

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count One ¶¶ 1-2; DPPs' Statement of Material Facts ISO Count Three ¶¶ 1-2.

43. Since 2000, Forest has expended hundreds of millions of dollars researching and developing Namenda.

Defendants' Evidence: Ex. 374, FRX-AT-01750551, Saunders Hr’g (Nov. 11, 2014) 280:14-20 (“[r]oughly \$2 billion [on royalties] ... [and] between the franchise of IR, XR and the fixed-dose combination and the pediatric study, ... roughly around \$500 million of R&D.”).

44. In December 2002, Forest submitted New Drug Application (“NDA”) No. 21-487 to the FDA, seeking approval to market memantine hydrochloride tablets (5mg and 10mg) – branded as Namenda – for the treatment of Alzheimer’s.

Defendants' Evidence: Ex. 8, FRX-AT-02660062; Ex. 9, FRX-AT-01784879.

Plaintiffs' Admissions: Am. Compl. ¶ 94.

45. On October 16, 2003, the FDA approved Forest's NDA for twice-daily Namenda immediate release ("IR") tablets for use in patients with moderate and severe Alzheimer's disease.

Undisputed Record Evidence: Ex. 9, FRX-AT-01784879.

Plaintiffs' Admissions: Am. Compl. ¶ 96.

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op. ¶ 38.

46. Immediate release drugs "release the active ingredient within a small period of time, typically less than 30-minutes."

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count One ¶ 6.

47. In January 2004, Forest commercially launched Namenda IR tablets in the United States.

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op. ¶ 38.

Defendants' Evidence: Ex. 10, FRX-AT-01775144.

Plaintiffs' Admissions: Am. Compl. ¶ 97.

#### **E. FDA Approval and Launch of Namenda XR**

48. Between 2006 and 2014, Forest invested approximately \$175 million in R&D for an improved version of Namenda—a once-daily extended release capsule, Namenda XR.

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op. ¶ 45.

Defendants' Evidence: Ex. 11, Declaration of William J. Meury (Oct. 21, 2014), ¶ 8, FRX-AT-01771984,.

49. Forest submitted NDA No. 22-525 for Namenda XR on September 14, 2009, seeking approval to market extended release memantine hydrochloride tablets (7mg, 14mg, 21mg, and 28mg) – branded as Namenda XR – for the treatment of Alzheimer’s.

Defendants’ Evidence: Ex. 12, FRX-AT-00526564; Ex. 13, FRX-AT-03642483.

50. Extended release drugs “release the active ingredient at a sustained and controlled release rate over a period of time. Typically extended release tablets and capsules release their ingredient with time periods of 8 hours, 12 hours, 16 hours, and 24 hours.”

Plaintiffs’ Admissions: DPPs’ Statement of Material Facts ISO Count One ¶ 6.

51. The FDA approved once-daily Namenda XR on June 21, 2010 for use in patients with moderate to severe Alzheimer’s disease.

Defendants’ Evidence: Ex. 13, FRX-AT-03642483.

Plaintiffs’ Admissions: Am. Compl. ¶ 146.

52. Forest launched Namenda XR in June 2013.

Plaintiffs’ Admissions: DPPs’ Statement of Material Facts ISO Count One ¶ 14.

Defendants’ Evidence: Ex. 14, FRX-AT-01909674.

#### **F. Forest’s Marketing of Namenda**

53. In the last 20 years, FDA has only approved five drugs for Alzheimer’s disease—the most recent one in 2003.

Public Document: FDA, *FDA Facilities Research on Earlier Stages of Alzheimer’s Disease*, 2 (Sep. 13, 2016), <https://www.fda.gov/ForConsumers/ConsumerUpdates/cm519875.htm>.

Defendants' Evidence: Ex. 324, Solomon (Sept. 7, 2017) Dep. 156:5-157:10 (“[T]here has not been a new chemical entity approved for the treatment of Alzheimer’s disease since memantine in 2003. 14 years, going on 15 years since a new product has been approved.”).

54. Pharmaceutical innovation is “both expensive and venturesome.”

Defendants' Evidence: Ex. 15, FRX-AT-01750103, October 21, 2014 Declaration of Mick Kolassa ¶ 81 (“Pharmaceutical innovation is the product of the brand-name, research-based pharmaceutical industry.”).

55. The average cost of developing a new drug is about \$1.3 billion, in part because so many drugs fail.

Defendants' Evidence: Ex. 322, FRX-AT-01751647, Cremieux (NYAG) Hr’g Tr. 833:3-834:13; Ex. 15, Kolassa (Oct. 21, 2014) Decl. ¶ 81 (“The investment necessary for [a] return [on pharmaceutical innovation] is estimated to be from \$800 million to over \$1 billion.”).

56. This is “particularly true” for Alzheimer’s disease treatments, where the development failure rate is approximately 99.6%.

Defendants' Evidence: Ex. 322, Cremieux (NYAG) Hr’g Tr. 833:3-834:13; Ex. 15, Kolassa (Oct. 21, 2014) Decl. ¶ 81 (“[F]or every 15,000 new compounds that are studied by research-based firms, only three will prove to be safe and effective enough to gain FDA approval.”); Ex. 325, Snyder Dep. 62:17-63:10 (“[T]here’s a 99 percent failure rate in clinical trials for Alzheimer’s disease products.”).

57. Merz owns ’703 patent for the application and use of Memantine.

Defendants' Evidence: Ex. 4, FRX-AT-01710620.

58. In June 2000, Forest obtained an exclusive license to U.S. Patent No. 5,061,703 (the ’703 patent held by Germany’s Merz Pharma GmbH & Co. KGaA).

Defendants' Evidence: Ex. 4, FRX-AT-01710620; Ex. 17, FRX-AT-01746478

Undisputed Record Evidence: Ex. 17, Amended Complaint, *The People of the State of New York v. Actavis, Plc and Forest Laboratories, LLC*, 14-Civ-7473 (S.D.N.Y. Sep. 14, 2014), ¶ 53.

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count One ¶ 3; DPPs' Statement of Material Facts ISO Count Three ¶ 3.

59. As part of that agreement, Forest obtained exclusive rights to market a memantine hydrochloride product in the United States under Merz's '703 patent.

Defendants' Evidence: Ex. 4, FRX-AT-01710620.

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count One ¶ 4; DPPs' Statement of Material Facts ISO Count Three ¶ 4.

60. Forest markets the prescription pharmaceutical memantine hydrochloride in the United States as Namenda®, Namenda XR®, and Namzaric®, a fixed-dose combination of memantine hydrochloride extended-release and donepezil hydrochloride.

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op. ¶ 2.

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count One ¶ 1; DPPs' Statement of Material Facts ISO Count Three ¶ 1.

Public Document: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/206439lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/206439lbl.pdf)

#### **G. Pediatric Exclusivity**

61. On July 7, 2011 Forest submitted a Proposed Pediatric Study Request ("PPSR") to the FDA, to initiate FDA's review and issuance of a Written Request to conduct studies to support the safety and efficacy of memantine HCl in pediatric patients with autism.

Defendants' Evidence: Ex.18, FRX-AT-03605359.

62. Forest submitted the PPSR to “obtain [FDA’s] agreement that there is an unmet medical need, and that memantine would be an appropriate product to develop and evaluate for the safe and effective treatment in children with autism ...”

Defendants’ Evidence: Ex. 326, Bray Dep. 100:1-17; Ex. 19, FRX-AT-03606011 at 6012 (“There are currently no medications specifically approved in the U.S. for the treatment of any of the core domains of autism.”).

63. At the time of the PPSR, memantine had been used off-label for the treatment of children with autism.

Defendants’ Evidence: Ex. 326, Bray Dep. 101:10-102:17; Ex. 19, FRX-AT-03606011 at 6012.

64. On January 25, 2012 FDA provided a Pediatric Written Request (“PWR”) to investigate the potential use of memantine for the treatment of the core social impairment symptoms in subjects with autism or autism spectrum disorder.

Undisputed Record Evidence: Ex. 19, FRX-AT-03606011.

65. On May 16, 2012 Forest notified FDA of its agreement to conduct the studies requested within the PWR and its plan to initiate the studies by the end of June 2012.

Defendants’ Evidence: Ex. 20, FRX-AT-03641863.

66. Forest spent approximately \$70 million dollars on clinical trials for the study of memantine in children.

Defendants’ Evidence: Ex. 61, FRX-AT-01731336, at -1340-41 (“By 2009, Forest began evaluating whether memantine could be approved for the treatment of pediatric autism. Forest conducted a series of clinical studies for this indication at a total cost of nearly \$70 million.”); Ex. 354, Saunders (NYAG) Dep. 318:4-23 (“Q: Do you have any

understanding of what is being conveyed here in the presentation to Merz? A. Yes, I think what we're trying to explain to Merz is that, you know, we made significant investments in R&D around Namenda XR in the fixed dose combination, including clinical studies. We did a pediatric study . . . in autism, which was I kind of remember about \$70 million or thereabouts, very expensive . . .").

67. FDA provided a Revised Written Request on May 29, 2013.

Undisputed Record Evidence: Ex. 21, FRX-AT-03642881.

68. FDA granted Forest Pediatric Exclusivity on June 16, 2014.

Public Documents: Pediatric Exclusivity Determinations List, August 2017, FDA, <https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/UCM514985.pdf>.

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count One ¶ 12; DPPs' Statement of Material Facts ISO Count Three ¶ 15.

69. The six-month pediatric exclusivity period ran from the expiration of the term of the '703 patent on April 11, 2015 to October 11, 2015.

Undisputed Record Evidence: Memorandum Decision and Order Granting in Part and Denying in Part Plaintiffs Motion for Collateral Estoppel and Partial Summary Judgment on Count One; Denying Plaintiffs' and Defendants' Motions for Partial Summary Judgment on Count Five, *In re Namenda Direct Purchaser Antitrust Litig.*, (S.D.N.Y. May 23, 2017), 15-cv-7488, ECF No. 252, at \*11.

Plaintiffs' Admissions: Am. Compl. ¶¶ 100-101.

## **H. Lexapro**

70. In September of 2002, Forest launched Lexapro, a serotonin reuptake inhibitor (SRRI) used for the treatment of major depression and generalized anxiety disorder.

Public Sources: Form 10-K filed May 29, 2009 at 9, *available at* <https://www.sec.gov/Archives/edgar/data/38074/000003807409000029/forest10k2009.htm>.

71. Escitalopram oxalate (“escitalopram”) is the active pharmaceutical ingredient in Lexapro.

Public sources: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/021323s047lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021323s047lbl.pdf)

72. Lexapro was developed by Forest and H. Lundbeck A/S (or Lundbeck), a Danish pharmaceutical firm which licensed the exclusive United States marketing rights to escitalopram to Forest.

Public sources: Form 10-K filed May 29, 2009 at 10, *available at* <https://www.sec.gov/Archives/edgar/data/38074/000003807409000029/forest10k2009.htm>.

#### **I. Teflaro/Ceftaroline**

73. Teflaro is a cephalosporin antibacterial indicated for the treatment of acute bacterial skin and skin structure infections and community-acquired bacterial pneumonia.

Public Sources: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2011/200327s001lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/200327s001lbl.pdf)

74. Ceftaroline fosamil (“ceftaroline”) is the active pharmaceutical ingredient in Teflaro.

Public Sources: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2011/200327s001lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/200327s001lbl.pdf); [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2010/200327Orig1s000ChemR.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/200327Orig1s000ChemR.pdf)

## II. GENERIC SETTLEMENTS: NO REVERSE PAYMENTS

### A. Terms of the Settlement Agreements with the Generic Defendants

75. On January 10, 2008, Forest filed a patent infringement lawsuit for infringement of the '703 patent against Cobalt Laboratories Inc. ("Cobalt"), Lupin Pharmaceuticals, Inc. and Lupin Ltd. (collectively "Lupin"), Orchid Pharmaceuticals Inc. and Orchid Chemicals & Pharmaceuticals Ltd (collectively "Orchid"), Teva Pharmaceuticals USA, Inc. ("Teva"), Upsher-Smith Laboratories, Inc. ("Upsher Smith"), and Wockhardt USA Inc. and Wockhardt Ltd. (collectively, "Wockhardt") after those generic companies submitted ANDAs for proposed generic versions of Namenda® that contained Paragraph IV certifications against Forest's '703 patent.

Public Document: Complaint, *Forest Labs., Inc. et al. v. Cobalt Labs. Inc., et al.*, 08-cv-021, D.I. 1 (D. Del.).

76. On January 25, 2008, Forest filed a patent infringement lawsuit for infringement of the '703 patent against, inter alia, Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Limited (collectively "Dr. Reddy's"), Amneal Pharmaceuticals ("Amneal"), Mylan Pharmaceuticals Inc. ("Mylan"), Sun Pharmaceutical Industries, Inc. ("Sun") (together with the generic defendants in the 08-00021 case, the "Generics") after those generic companies submitted ANDAs for proposed generic versions of Namenda® that contained Paragraph IV certifications against Forest's '703 patent.

Public Document: Complaint, *Forest Labs., Inc., et al., v. Dr. Reddy's Labs., Inc., et al.*, 08-cv-052, D.I. 1 (D. Del.); *see id.*, D.I. 91, Order of Consolidation (these two cases were eventually consolidated).

77. By submitting Paragraph IV certifications, the Generics requested FDA approval to market their generic product prior to the expiry of the '703 patent on April 11, 2015.

Public Document: 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

78. On July 2, 2009, Magistrate Judge Stark issued a Report & Recommendation Regarding Claim Construction.

Public Documents: Ex. 139, '703 Patent Litigation, Dkt. No. 373

79. Judge Stark "largely sided with Plaintiffs" [i.e., Forest], adopting Forest's positions on 9 of the 13 disputed issues, and rejecting the generics' proposals on the remaining 4 in favor of his own constructions.

Public Documents: *See generally* Ex. 139, '703 Patent Litigation, Dkt. No. 373.

Defendants' Documents: Ex. 5, McKelvie Rep. ¶ 56

Plaintiffs' Admissions: Ex. 140, Direct Purchaser Class Plaintiffs' Amended Responses to Forest's Request for Admission No. 12, dated Jul. 19, 2017.

80. Following Judge Stark's R&R and Judge Sleet's memorandum and order, Forest and the Generics entered into Settlement Agreements.

Defendants' Evidence: Ex. 22, FRX-AT-00000218, Amneal Settlement Agreement, dated September 1<sup>st</sup>, 2009; Ex. 23, FRX-AT-00000274, Apotex Settlement Agreement, dated September 8<sup>th</sup>, 2009; Ex. 24, FRX-AT-00000148, Upsher-Smith Settlement Agreement, dated September 8<sup>th</sup>, 2009; Ex. 25, FRX-AT-00000076, Wockhardt Settlement Agreement, dated September 10<sup>th</sup>, 2009; Ex. 26, FRX-AT-00000112, Sun Settlement Agreement, dated October 9<sup>th</sup>, 2009; Ex. 27, FRX-AT-00000038, Cobalt Settlement Agreement, dated October 15<sup>th</sup>, 2009; Ex. 28, FRX-AT-00000184, Teva Settlement Agreement, dated November 3<sup>rd</sup>, 2009; Ex. 29, FRX-AT-00000001, Dr.

Reddy's Settlement Agreement, dated November 13<sup>th</sup>, 2009; Ex. 30, FRX-AT-00000309, Torrent Settlement Agreement, dated December 7<sup>th</sup>, 2009; Ex. 31, FRX-AT-00000340, Lupin Settlement Agreement, dated December 11<sup>th</sup>, 2009; Ex. 32, FRX-AT-00000380, Orchid Settlement Agreement, dated March 23<sup>rd</sup>, 2010; Ex. 33, FRX-AT-00000428, Mylan Settlement Agreement, dated July 21<sup>st</sup>, 2010.

81. As described in more detail below, for each of the Generics, the licenses agreements contained specific clauses that allowed the Generics to enter even earlier in the event that other generic manufacturers entered the market with a generic memantine product ("Generic Entry Early Acceleration Clauses").

Defendant's documents: *Id.*

**Amneal**

82. Forest's settlement with Amneal allows Amneal to launch a generic memantine hydrochloride product the later of "3 calendar months prior to the expiration of the '703 patent, including any extensions and/or pediatric exclusivity" or "the date that Amneal obtains final approval from the FDA."

Defendants' Evidence: Ex. 22, Amneal Settlement Agreement, Exhibit B (License Agreement), at §§ 1.14, 2.1, 3.2.

83. Amneal was eligible to begin marketing (per the settlement agreement, without accounting for any required FDA approval) a generic memantine hydrochloride product by July 11, 2015.

Defendants' Evidence: Ex. 22, Amneal Settlement Agreement, Exhibit B (License Agreement), at §§ 1.14, 2.1, 3.2.

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count Three ¶ 30.

84. Under license agreement Amneal represented that “its attorney fees and costs to date in the Action have exceeded \$150,000,” and Forest agreed to pay Amneal \$150,000 to defray a portion of the paid attorney fees and costs and to reflect a portion of the saved attorney fees and costs that Forest would not have to incur in the Patent ‘703 litigation.

Defendants’ Evidence: Ex. 22, Amneal Settlement Agreement, Exhibit B (License Agreement), at § 2.5.

85. Amneal’s litigation costs were \$450,000.

Undisputed Record Evidence: Ex. 327, Gupta (Amneal) Dep. 112:21-113:22.

86. Amneal’s license agreement contained Generic Entry Early Acceleration Clauses that allowed Amneal to launch its memantine product even earlier if (i) Forest entered into an agreement with another generic company; (ii) another generic company obtained a final court decision of non-infringement and/or invalidity of the ‘703 patent; or (iii) another generic company launches “at risk.”

Defendants’ Evidence: Ex. 22, Amneal Settlement Agreement, Exhibit B (License Agreement), at §§ 4.3, 4.4, 4.5.

87. Amneal negotiated the terms of Generic Entry Early Acceleration Clauses in its license agreement with Forest.

Third Party Testimony: Ex. 327, Gupta (Amneal) Dep. 118:11-119:12 (“Q: This settlement agreement that we’re looking at here, this is the result of back and forth negotiations between Forest and Ameal, right? A: Yes.”).

**Apotex**

88. Forest's settlement with Apotex allows Apotex to launch a generic memantine hydrochloride product the later of "3 calendar months prior to the expiration of the '703 patent, including any extensions and/or pediatric exclusivity" or "the date that Apotex obtains final approval from the FDA."

Defendants' Evidence: Ex. 23, Apotex Settlement Agreement, Exhibit B (License Agreement), at §§ 1.14, 2.1, 3.2.

89. Apotex was eligible to begin marketing (per the settlement agreement, without accounting for any required FDA approval) a generic memantine hydrochloride product by July 11, 2015.

Defendants' Evidence: Ex. 23, Apotex Settlement Agreement, Exhibit B (License Agreement), at §§ 1.14, 2.1, 3.2.

90. Apotex's license agreement contained Generic Entry Early Acceleration Clauses that allowed Apotex to launch its memantine product even earlier if (i) Forest entered into an agreement with another generic company; (ii) another generic company obtained a final court decision of non-infringement and/or invalidity of the '703 patent; or (iii) another generic company launches "at risk".

Defendants' Evidence: Ex. 23, Apotex Settlement Agreement, Exhibit B (License Agreement), at §§ 4.3, 4.4, 4.5.

91. Apotex negotiated the terms of the Generic Entry Early Acceleration Clauses in its license agreement with Forest.

Undisputed Record Evidence: Ex. 34, KE00000169 ("As discussed, Forest and Merz are unwilling to pay Apotex a non-first-file, any attorney fees."); Ex. 35, KE00000135 ("As

you can see from changes we are only trying to maintain the same position we would have been in if we had not filed.”).

**Cobalt**

92. Forest’s settlement with Cobalt allows Cobalt to launch a generic memantine hydrochloride product the later of “3 calendar months prior to the expiration of the ’703 patent, including any extensions and/or pediatric exclusivity” or “the date that Cobalt obtains final approval from the FDA.”

Defendants’ Evidence: Ex. 27, Cobalt Settlement Agreement, Exhibit B (License Agreement), at §§ 1.15, 2.1, 3.2.

93. Cobalt was eligible to begin marketing (per the settlement agreement, without accounting for any required FDA approval) a generic memantine hydrochloride product by July 11, 2015.

Defendants’ Evidence: Ex. 27, Cobalt Settlement Agreement, at Ex. B (License Agreement) §§1.15, 2.1, 2.2, 3.2.

94. Under the license agreement Cobalt represented that “its attorney fees and costs to date in the Action have exceeded \$1,500,000,” and Forest agreed to pay Cobalt \$1,500,000 to defray a portion of the paid attorney fees and costs and to reflect a portion of the saved attorney fees and costs that Forest would not have to incur in the Patent ’703 litigation.

Defendants’ Evidence: Ex. 27, Cobalt Settlement Agreement, at Ex. B (License Agreement) § 2.5.

95. Cobalt’s license agreement contained Generic Entry Early Acceleration Clauses that allowed Cobalt to launch its memantine product even earlier if (i) Forest entered into an agreement with another generic company; (ii) another generic company obtained a final court

decision of non-infringement and/or invalidity of the '703 patent; or (iii) another generic company launches "at risk."

Defendants' Evidence: Ex. 27, Cobalt Settlement Agreement, at Ex. B (License Agreement) §§ 4.3, 4.4, 4.5 .

**Dr. Reddy's**

96. Forest's settlement with Dr. Reddy's allows Dr. Reddy's to launch a generic memantine hydrochloride product the later of "3 calendar months prior to the expiration of the '703 patent, including any extensions and/or pediatric exclusivity" or "the date that DRL obtains final approval from the FDA."

Defendants' Evidence: Ex. 29, Dr. Reddy's Settlement Agreement, at Ex. B (License Agreement) §§ 1.16, 2.1, 3.2.

97. Dr. Reddy's was eligible to begin marketing (per the settlement agreement, without accounting for any required FDA approval) a generic memantine hydrochloride product by July 11, 2015.

Defendants' Evidence: Ex. 29, Dr. Reddy's Settlement Agreement, at Ex. B (License Agreement) §§ 1.16, 2.1, 3.2.

Plaintiffs' Admissions: DPPs' Statement of Material Facts in Supp. of Mot. for Partial Sum. J. on Count Three, Dkt. 147 ¶ 44.

98. Under the license agreement Dr. Reddy "shall provide Plaintiffs with an accounting of DRL's expended legal fees and costs associated with the Action," and Forest would pay Dr. Reddy's an amount up to a maximum total reimbursement of \$1,000,000 to defray a portion of the paid attorney fees and costs.

Defendants' Evidence: Ex. 29, Dr. Reddy's Settlement Agreement, at Ex. B (License Agreement) § 2.5.

99. DRL's litigation costs totaled \$849,732.34.

Defendants' Evidence: Ex. 36, FRX-AT-04231043; Ex. 37, FRX-AT-04229715, at - 9716; Ex. 38, FRX-AT-03634534.

Undisputed Record Evidence: Ex. 328, McCormick (Dr. Reddy's) Dep. 107:15-119:16.

100. Dr. Reddy's license agreement contained Generic Entry Early Acceleration Clauses that allowed Dr. Reddy's to launch its memantine product even earlier if (i) Forest entered into an agreement with another generic company; (ii) another generic company obtained a final court decision of non-infringement and/or invalidity of the '703 patent; or (iii) another generic company launches "at risk."

Defendants' Evidence: Ex. 29, Dr. Reddy's Settlement Agreement, at Ex B (License Agreement) §§ 4.3, 4.4, 4.5

101. Dr. Reddy's negotiated the terms of the Generic Entry Early Acceleration Clauses in its license agreement with Forest.

Defendants' Evidence: Ex. 39, FRX-AT-03628446 ("Attached is a revised agreement that we believe addresses the concerns you raised during our discussion.").

Undisputed Record Evidence: Ex. 328, McCormick (Dr. Reddy's) Dep. 157:4-24.

### **Lupin**

102. Forest's settlement with Lupin allows Lupin to launch a generic memantine hydrochloride product the later of "3 calendar months prior to the expiration of the '703 patent,

including any extensions and/or pediatric exclusivity” or “the date that Lupin obtains final approval from the FDA.”

Defendants’ Evidence: Ex. 31, Lupin Settlement Agreement, at Ex. B (License Agreement) §§ 1.12, 2.1, 3.2.

103. Lupin was eligible to begin marketing (per the settlement agreement, without accounting for any required FDA approval) a generic memantine hydrochloride product by July 11, 2015.

Defendants’ Evidence: Ex. 31, Lupin Settlement Agreement, at Ex. B (License Agreement) §§ 1.12, 2.1, 3.2.

Plaintiffs’ Admissions: DPPs’ Statement of Material Facts ISO Count Three ¶ 58.

104. Under the license agreement Lupin represented that “its attorney fees and costs to date and related internal costs of support and assistance in the Action has exceeded \$1,000,000,” and Forest agreed to pay Lupin \$1,000,000 to defray a portion of the paid attorney fees and costs and to reflect a portion of the saved attorney fees and costs that Forest would not have to incur in the Patent ‘703 litigation.

Defendants’ Evidence: Ex. 31, Lupin Settlement Agreement, at Ex. B (License Agreement) § 2.5.

105. Lupin’s license agreement contained Generic Entry Early Acceleration Clauses that allowed Lupin to launch its memantine product even earlier if (i) Forest entered into an agreement with another generic company; (ii) another generic company obtained a final court decision of non-infringement and/or invalidity of the ‘703 patent; or (iii) another generic company launches “at risk.”

Defendants' Evidence: Ex. 31, Lupin Settlement Agreement, at Ex. B (License Agreement) §§ 4.4, 4.5, 4.6.

106. Lupin negotiated the terms of the Generic Entry Early Acceleration Clauses in its license agreement with Forest.

Defendants' Evidence: Ex. 40, FRX-AT-04319774, at -9778 (“We agree with all of your proposed revisions to the settlement agreement.”).

**Mylan**

107. Forest’s settlement with Mylan allows Mylan to launch a generic memantine hydrochloride product the later of “three (3) calendar months prior to the expiration of the ’703 patent, including any extensions and/or pediatric exclusivity” or “the date that Mylan obtains final approval from the FDA.”

Defendants' Evidence: Ex. 33, Mylan Settlement Agreement, at Ex. B (License Agreement) §§ 1.13, 2.1, 3.2.

108. Mylan was eligible to begin marketing (per the settlement agreement, without accounting for any required FDA approval) a generic memantine hydrochloride product by July 11, 2015.

Defendants' Evidence: Ex. 33, Mylan Settlement Agreement, at Ex. B (License Agreement) §§ 1.13, 2.1, 3.2.

Plaintiffs' Admissions: DPPs’ Statement of Material Facts ISO Count Three ¶ 72.

109. Under the license agreement Mylan represented that “its attorney fees and costs to date in the Action have exceeded \$2,000,000,” and Forest agreed to pay Mylan \$2,000,000 to defray a portion of the paid attorney fees and costs and to reflect a portion of the saved attorney fees and costs that Forest would not have to incur in the Patent ‘703 litigation.

Defendants' Evidence: Ex. 33, Mylan Settlement Agreement, at Ex. B (License Agreement) § 2.5.

110. Mylan's litigation costs exceeded \$2 million.

Undisputed Record Evidence: Ex. 329, Silber (Mylan) Dep. 12:21-16:24; Ex. 41, MYLMEMA-D-000001.

111. Mylan's license agreement contained Generic Entry Early Acceleration Clauses that allowed Mylan to launch its memantine product even earlier if (i) Forest entered into an agreement with another generic company; (ii) another generic company obtained a final court decision of non-infringement and/or invalidity of the '703 patent; or (iii) another generic company launches "at risk."

Defendants' Evidence: Ex. 33, Mylan Settlement Agreement, at Ex. B (License Agreement), at §§ 4.3, 4.4, 4.5.

Undisputed Record Evidence: Ex. 329, Silber Dep. 16:20-24

### **Orchid**

112. Forest's settlement with Orchid allows Orchid to launch a generic memantine hydrochloride product the later of "3 calendar months prior to the expiration of the '703 patent, including any extensions and/or pediatric exclusivity" or "the date that Orchid obtains final approval from the FDA."

Defendants' Evidence: Ex. 32, Orchid Settlement Agreement, at Ex. B (License Agreement) §§ 1.14, 2.1, 3.2.

113. Orchid was eligible to begin marketing (per the settlement agreement, without accounting for any required FDA approval) a generic memantine hydrochloride product by July 11, 2015.

Defendants' Evidence: Ex. 32, Orchid Settlement Agreement, at Ex. B (License Agreement) §§ 1.14, 2.1, 3.2.

114. Under license agreement Orchid represented that “its attorney fees and costs to date in the Action ... have exceeded \$2,000,000” and Forest agreed to pay Orchid \$2,000,000 to defray a portion of the paid attorney fees and costs and to reflect a portion of the saved attorney fees and costs that Forest would not have to incur in the Patent ‘703 litigation.

Defendants' Evidence: Ex. 32, Orchid Settlement Agreement, at Ex. B (License Agreement) § 2.5.

115. Orchid’s license agreement contained Generic Entry Early Acceleration Clauses that allowed Orchid to launch its memantine product even earlier if (i) Forest entered into an agreement with another generic company; (ii) another generic company obtained a final court decision of non-infringement and/or invalidity of the ‘703 patent; or (iii) another generic company launches “at risk.”

Defendants' Evidence: Ex. 32, Orchid Settlement Agreement, at Ex. B (License Agreement) §§ 4.3, 4.4, 4.5.

116. Orchid negotiated the terms of the Generic Entry Early Acceleration Clauses in its license agreement with Forest.

Defendants' Evidence: Ex. 42, KE00000830 (“We will need to discuss a few substantive issues. ... [W]e can offer you a choice between two types of provisions.”); Ex. 43, FRX-AT-03629461.

**Sun**

117. Forest's settlement with Sun allows Sun to launch a generic memantine hydrochloride product the later of "3 calendar months prior to the expiration of the '703 patent, including any extensions and/or pediatric exclusivity" or "the date that Sun obtains final approval from the FDA."

Defendants' Evidence: Ex. 26, Sun Settlement Agreement, Ex. B (License Agreement) §§ 1.12, 2.1, 3.2.

118. Sun was eligible to begin marketing (per the settlement agreement, without accounting for any required FDA approval) a generic memantine hydrochloride product by July 11, 2015.

Defendants' Evidence: Ex. 26, Sun Settlement Agreement, Ex. B (License Agreement), at §§ 1.12, 2.1, 3.2.

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count Three ¶ 99.

119. Under license agreement Sun represented that "its attorney fees and costs to date in the Action have exceeded \$1,500,000" and Forest agreed to pay Sun \$1,500,000 to defray a portion of the paid attorney fees and costs and to reflect a portion of the saved attorney fees and costs that Forest would not have to incur in the Patent '703 litigation.

Defendants' Evidence: Ex 26, Sun Settlement Agreement, at Ex. B (License Agreement) § 2.5.

120. Sun's litigation costs exceeded \$1,500,000.

Undisputed Record Evidence: Ex. 330, Nadkarni (Sun) Dep. 125:3-126:7.

121. Sun's license agreement contained Generic Entry Early Acceleration Clauses that allowed Sun to launch its memantine product even earlier if (i) Forest entered into an agreement with another generic company; (ii) another generic company obtained a final court decision of non-infringement and/or invalidity of the '703 patent; or (iii) another generic company launches "at risk."

Defendants' Evidence: Ex. 26, Sun Settlement Agreement, at Ex. B (License Agreement) §§ 4.3, 4.4, 4.5.

122. Sun negotiated the terms of the Generic Entry Early Acceleration Clauses in its license agreement with Forest.

Defendants' Evidence: Ex. 44, FRX-AT-03633799 at 818-820; Ex. 45, FRX-AT-03633765.

Undisputed Record Evidence: Ex. 330, Nadkarni (Sun) Dep. 127:9-128:7.

### **Teva**

123. Forest's settlement with Teva allows Teva to launch a generic memantine hydrochloride product "three (3) calendar months prior to the later of (a) expiration of the '703 Patent, including any extensions thereof; and (b) any pediatric exclusivity period attached to the '703 Patent, whether such extension or pediatric exclusivity was granted before, on, or after the Execution Date."

Defendants' Evidence: Ex. 28, Teva Settlement Agreement, at Ex. B (License Agreement) §§ 1.14, 2.1, 3.2.

124. Teva was eligible to begin marketing (per the settlement agreement, without accounting for any required FDA approval) a generic memantine hydrochloride product by July 11, 2015.

Defendants' Evidence: Ex. 28, Teva Settlement Agreement, at Ex. B (License Agreement) §§ 1.14, 2.1, 3.2.

125. Under the license agreement Teva represented that “its attorney fees and costs to date in the Action have exceeded \$1,000,000,” and Forest agreed to pay Teva \$1,000,000 to defray a portion of the paid attorney fees and costs and to reflect a portion of the saved attorney fees and costs that Forest would not have to incur in the Patent ‘703 litigation.

Defendants' Evidence: Ex. 28, Teva Settlement Agreement, at Ex. B (License Agreement) § 2.6.

126. Teva’s litigation costs exceeded \$1,000,000.

Undisputed Record Evidence: Ex. 331, Rabinovic (Teva) Dep. 36:19-38:9; 86:19-87:9.

127. Teva’s license agreement contained Generic Entry Early Acceleration Clauses that allowed Teva to launch its memantine product even earlier if (i) Forest entered into an agreement with another generic company; (ii) another generic company obtained a final court decision of non-infringement and/or invalidity of the ‘703 patent; or (iii) another generic company launches “at risk.”

Defendants' Evidence: Ex. 28, Teva Settlement Agreement, at Ex. B (License Agreement), at §§ 4.3, 4.4, 4.5.

128. Teva negotiated the terms of the Generic Entry Early Acceleration Clauses in its license agreement with Forest.

Defendants' Evidence: Ex. 46, FRX-AT-03627793; Ex. 47, FRX-AT-03627794 , at - 7816-18.

Undisputed Record Evidence: Ex. 331, Rabinovic (Teva) Dep. 42:19-45:7.

### **Upsher-Smith**

129. Forest's settlement with Upsher-Smith allows Upsher-Smith to launch a generic memantine hydrochloride product the later of "3 calendar months prior to the expiration of the '703 patent, including any extensions and/or pediatric exclusivity" or "the date that Upsher-Smith obtains final approval from the FDA."

Defendants' Evidence: Ex. 24, Upsher-Smith Settlement Agreement, at Ex. B (License Agreement) §§ 1.13, 2.1, 3.2.

130. Upsher-Smith was eligible to begin marketing (per the settlement agreement, without accounting for any required FDA approval) a generic memantine hydrochloride product by July 11, 2015.

Defendants' Evidence: Ex. 24, Upsher-Smith Settlement Agreement, at Ex. B (License Agreement) §§ 1.13, 2.1, 3.2.

131. Under the license agreement Upsher-Smith represented that "its attorney fees and costs to date in the Action have exceeded \$600,000," and Forest agreed to pay Upsher-Smith \$600,000 to defray a portion of the paid attorney fees and costs and to reflect a portion of the saved attorney fees and costs that Forest would not have to incur in the Patent '703 litigation.

Defendants' Evidence: Ex. 24, Upsher-Smith Settlement Agreement, at Ex. B (License Agreement) § 2.5.

132. Upsher-Smith's license agreement contained Generic Entry Early Acceleration Clauses that allowed Upsher-Smith to launch its memantine product even earlier if (i) Forest entered into an agreement with another generic company; (ii) another generic company obtained a final court decision of non-infringement and/or invalidity of the '703 patent; or (iii) another generic company launches "at risk."

Defendants' Evidence: Ex. 24, Upsher-Smith Settlement Agreement, at Ex. B (License Agreement) §§ 4.3, 4.4, 4.5.

133. Upsher-Smith negotiated the terms of the Generic Entry Early Acceleration Clauses in its license agreement with Forest.

Defendants' Evidence: Ex. 48, FRX-AT-03626587, at -6588 ("here's a recap of the big-picture issues that USL would like to address with appropriate revisions or other assurances"); Ex. 49, FRX-AT-03626726, at -6727.

### **Wockhardt**

134. Forest's settlement with Wockhardt allows Wockhardt to launch a generic memantine hydrochloride product the later of "3 calendar months prior to the expiration of the '703 patent, including any extensions and/or pediatric exclusivity" or "the date that Wockhardt obtains final approval from the FDA."

Defendants' Evidence: Ex. 25, Wockhardt Settlement Agreement, at Ex. B (License Agreement) § 1.12, 2.1, 3.2.

135. Wockhardt was eligible to begin marketing (per the settlement agreement, without accounting for any required FDA approval) a generic memantine hydrochloride product by July 11, 2015.

Defendants' Evidence: Ex. 25, Wockhardt Settlement Agreement, at Ex. B (License Agreement) § 1.12, 2.1, 3.2.

136. Under the license agreement Wockhardt represented that “its attorney fees and costs to date in the Action have exceeded \$1,000,000,” and Forest agreed to pay Wockhardt \$1,000,000 to defray a portion of the paid attorney fees and costs and to reflect a portion of the saved attorney fees and costs that Forest would not have to incur in the Patent ‘703 litigation.

Defendants' Evidence: Ex. 25, Wockhardt Settlement Agreement, at Ex. B (License Agreement) § 2.5.

137. Wockhardt’s litigation fees were approximately \$1.85 million.

Undisputed Record Evidence: Ex. 351, Venkatesan (Wockhardt) Dep. 103:3-104:22.

138. Wockhardt’s license agreement contained Generic Entry Early Acceleration Clauses that allowed Wockhardt to launch its memantine product even earlier if (i) Forest entered into an agreement with another generic company; (ii) another generic company obtained a final court decision of non-infringement and/or invalidity of the ‘703 patent; or (iii) another generic company launches “at risk.”

Defendants' Evidence: Ex. 25, Wockhardt Settlement Agreement, at Ex. B (License Agreement) §§ 4.3, 4.4, 4.5.

139. Wockhardt negotiated the terms of the Generic Entry Early Acceleration Clauses in its license agreement with Forest.

Defendants' Evidence: Ex. 50, FRX-AT-03626934 (“We believe this draft strikes a fair balance of our respective clients.”); Ex. 51, FRX-AT-03626968 at 988-989.

**Torrent**

140. Forest's settlement with Torrent allows Torrent to launch a generic memantine hydrochloride product on the later of "(a) the expiration date of the '703 Patent, including any extensions and/or pediatric exclusivity, whether granted before, on or after the Effective Date; or (b) the date that Torrent obtains final approval from the FDA."

Defendants' Evidence: Ex. 30, Torrent Settlement Agreement, at Ex. B (License Agreement) §§ 1.11, 2.1, 3.2.

141. Torrent was eligible to begin marketing (per the settlement agreement, without accounting for any required FDA approval) a generic memantine hydrochloride product by October 11, 2015, upon the expiry of Forest's pediatric exclusivity.

Defendants' Evidence: Ex. 30, Torrent Settlement Agreement, at Ex. B (License Agreement) §§ 1.11, 2.1, 3.2.

142. The FDA approved the Torrent generic memantine hydrochloride product on October 13, 2015; the first business day after the expiry of Forest's pediatric exclusivity.

Public Document: FDA, *Memantine Hydrochloride*, Drugs@FDA, <https://www.accessdata.fda.gov/scripts/cder/daf/indEx.cfm?event=overview.process&ApplNo=200155>.

143. Torrent's license agreement contained Generic Entry Early Acceleration Clauses that allowed Torrent to launch its memantine product even earlier if (i) Forest entered into an agreement with another generic company; (ii) another generic company obtained a final court decision of non-infringement and/or invalidity of the '703 patent; or (iii) another generic company launches "at risk."

Defendants' Evidence: Ex. 30, Torrent Settlement Agreement, at Ex. B (License Agreement) §§ 4.3, 4.4, 4.5.

144. Torrent negotiated the terms of the Generic Entry Early Acceleration Clauses in its license agreement with Forest.

Defendants' Evidence: Ex. 52, FRX-AT-04318722; Ex. 53, FRX-AT-04318750 at 764-766.

145. Forest's expert opinion that the generic settlement agreements were not anticompetitive is un rebutted, except with respect to Mylan.

Defendants' Evidence: Ex. 54, Expert Report of Dr. Lona Fowdur ("Fowdur Rep.") ¶ 41, n. 103.

Plaintiffs' Admissions: Ex. 335, Elhauge (Sept. 29) Dep. 37:15-39:15; Ex. 368, Elhauge (Nov. 10) Dep. 309:15-310:251; Ex. 363, Lamb (Oct. 6) Dep. 231:20-21 ("[T]he reverse payment between Forest and Mylan, as I understand, is the only reverse payment[sic] challenged to be anticompetitive by the Plaintiffs."). Not a single one of Plaintiffs' eight experts opine that any settlement was anticompetitive, except for the settlement agreement with Mylan. *See generally* Ex. 55, Amended Reply Expert Report of Ernst R. Berndt, Ph.D. ("Berndt Reply") ¶ 1; Ex. 56, Amended Expert Reply Report, Dr. Russell Lamb ("Lamb Reply") ¶¶ 2-3.

#### **B. Forest's Search for a Secondary Supplier of Ceftriaxone**

146. Ceftriaxone is the active pharmaceutical ingredient ("API") in the brand drug Teflaro.

Public Document: FDA, *Ceftriaxone Fosamil*, Drugs@FDA, [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2011/200327s001lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/200327s001lbl.pdf).

147. Forest obtained the worldwide rights (excluding Japan) to Teflaro in 2007 when it acquired Cerexa, Inc.

Defendants' Evidence: Ex. 332, Carnevale Dep. 38:14-24.

Public Document: Allergan, *Allergan Receives FDA Approval of Teflaro® (ceftaroline fosamil) for Pediatric Patients*, <https://www.allergan.com/investors/news/thomson-reuters/allergan-receives-fda-approval-of-teflaro-ceftaro>.

148. On April 30, 2008, Forest entered a Development and Supply Agreement with ACS Dobfar (“Dobfar”) for Ceftaroline.

Defendants’ Evidence: Ex. 57, FRX-AT-03522446 at 447-448.

149. Dobfar acted as Forest’s primary supplier of Ceftaroline API.

Defendants’ Evidence: Ex. 332, Carnevale Dep. 144:8-10 (“Dobfar is our primary supplier for ceftaroline.”); Ex. 324, Solomon (Sept. 7) Dep. 214:2-215:20 (“[T]he supply arrangement we made with Orchid was highly favorable to us at a much lower price than what we were then paying to Dobfar, the Italian company who was our sole supplier of ceftaroline.”); Ex. 333, Mears Dep. 181:15-184:7 (“[W]e had a primary supplier in ACS Dobfar.”).

150. Forest’s agreement with Dobfar contemplated a price of €7,37 per vial (or \$9.95, based on the exchange rate on March 23, 2010 – €1,00 = \$1.35).

Defendants’ Evidence: Ex. 57, FRX-AT-03522446 at 450 (§ 5 “Pricing”).

Defendants’ Evidence: Ex. 324, Solomon (Sept. 7) Dep. 214:2-215:20 (“At that point we were paying over \$10 a vial to Dobfar.”).

Public Document: X-Rates, *Historic Lookup: EUR to USD Conversion*, <http://www.x-rates.com/historical/?from=EUR&amount=1&date=2010-03-23>

151. Although Forest had secured a primary supplier of ceftaroline, at the time, Forest sought to dual source its drug products in order to avoid shortages.

Defendants’ Evidence: Ex. 332, Carnevale Dep. 38:14-24, 77:6-78:5; Ex. 333, Mears Dep. 181:15-184:7 (“[L]ooking for second source was something, as I mentioned, we did for all of our drugs.”).

152. As of at least September 3, 2008, Forest was looking for a secondary supplier of ceftaroline API.

Defendants' Evidence: Ex. 332, Carnevale Dep. 186:24-4 (“Q: So is it fair to say that as of September 3, 2008, Forest was looking for a secondary supplier of ceftaroline API? A: Yes.”).

Defendants' Evidence: Ex. 58, FRX-AT-03655713.

153. Because ceftaroline is a cephalosporin antibacterial, the FDA recommends that a manufacturing facility has an area that is dedicated to manufacturing ceftaroline and that is “completely and comprehensively” separated from areas of the facility in which other products are manufactured.

Public Document: FDA, *Guidance for Industry, Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination*, <https://www.fda.gov/downloads/drugs/guidances/ucm246958.pdf> (“FDA recommends that the area in which any [cephalosporins are] manufactured be separated from areas in which any other products are manufactured, and have independent air handling system” and that “the section of a facility dedicated to manufacturing [cephalosporins] be isolated (i.e., completely and comprehensively separated) from areas in the facility in which non-penicillin products are manufactured.”).

154. While searching for a secondary supplier of ceftaroline, Forest recognized that there were only a limited number of companies that were equipped to manufacture ceftaroline according to FDA guidelines and Forest’s own internal standards.

Defendants' Evidence: Ex. 324, Solomon (Sept. 7) Dep. 215:22-218:9 (“You’re talking about a sterile cephalosporin so there are a limited number of supplies globally who can make sterile cephalosporins. It’s a very specified manufacturing and any company that does it can’t do anything else because once you’ve – from the FDA’s point of view, once you’ve contaminated a facility with these cephalosporins, you can’t use it for any other kind of manufacturing so there are very few facilities globally. They are highly dedicated and they are difficult to find.”); Ex. 333, Mears Dep. 181:15-184:7 (“Ceftaroline was somewhat unique, in the sense that it was a sterile manufacturing suite for cephalosporin . . . and the ceftaroline sourcing project in terms of looking for second source was

something, as I mentioned, we did for all of our drugs, but it was particularly challenging in the antibiotics space. I mean, antibiotics are notoriously underfunded. It is hard to find supply partners. It is hard to find supply partners that have the right size facility and sterile capabilities that are stable. And Orchid was one of those candidates. And so I was very interested in having a positive business relationship on ceftaroline with Orchid.”); Ex. 332, Carnevale 40:21-17 (“And since this was an antibiotic, you needed to have a facility that was, you know, very clean and qualified and was able to make antibiotics in the way we wanted it to be made.”).

155. Forest began negotiating with Orchid to be a potential secondary supplier of ceftaroline API in February 2008.

Defendants’ Evidence: Ex. 59, FRX-AT-04390036 at 38.

156. On November 24, 2008 Forest and Orchid executed a Memo of Understanding (“MOU”) for the purpose of “explor[ing] a collaborative relationship for the long term development, manufacture and supply of Ceftaroline.”

Defendants’ Evidence: Ex. 60, FRX-AT-04624979.

157. The MOU provided that Orchid would synthesize 30 grams of sterile API in three batches, and if Forest approved the batches, the parties would begin negotiating a definitive agreement for Orchid to be a supplier of ceftaroline.

Defendants’ Evidence: Ex. 60, FRX-AT-04624979.

158. Forest continued to consider other potential secondary suppliers of ceftaroline API throughout 2009.

Defendants’ Evidence: Ex. 332, Carnevale Dep. 38:14-39:5 (“Q. Who were the other potential secondary suppliers? A. We looked at a number of companies. Dr. Reddy’s, Dr. Reddy’s Laboratories. Lupin. Another company called Wockhardt.”), 179:17-181:5 (acknowledging the same three companies and Orchid as possible secondary suppliers and noting that there may have been others considered).

159. In May 2009, Forest employees went to India to visit the facilities of Orchid, Dr. Reddy's, Lupin, and Wockhardt to evaluate them as potential ceftaroline API suppliers.

Defendants' Evidence: Ex. 332, Carnevale Dep. 42:12-43:6

160. Forest believed Orchid had "the best looking and best facility for a supplier [, and since [ceftaroline] was an antibiotic, [Forest] needed to have a facility that was, you know, very clean and qualified and was able to make antibiotics in the way [Forest] wanted it to be made."

Defendants' Evidence: Ex. 332, Carnevale Dep. 39:21-40:17.

### **C. The Ceftaroline Supply Agreement with Orchid**

161. On March 23, 2010, Forest and Orchid executed the Development and Supply Agreement for Ceftaroline Binding Term Sheet.

Defendants' Evidence: Ex. 62, FRX-AT-00000417 ("Ceftaroline Term Sheet"), at 426

Plaintiffs' Admissions: DPPs' Mem. in Opp'n to Mot. to Dismiss, Dkt. No. 69 at 24.

162. Pursuant to the Ceftaroline Term Sheet, Forest would pay Orchid milestone payments up to \$840,000 (the "Development Fee") in consideration for Orchid's manufacture of Development Batches.

Defendants' Evidence: Ex. 57, Ceftaroline Term Sheet, § 6.

Plaintiffs' Admissions: DPPs' Memo. in Opp'n to Mot. to Dismiss, Dkt. No. 69 at 24.

163. The Development Fee was to be paid according to a schedule – Forest agreed to pay Orchid \$210,000 upon the execution of the Term Sheet, \$420,000 upon timely completion of

the manufacture of three batches of 35,000 vials each, and \$210,000 upon completion of applicable stability work and all supporting documentation needed for Forest's regulatory filings.

Defendants' Evidence: Ex. 57, Ceftaroline Term Sheet, § 6.

Plaintiffs' Admissions: Ex. 375, DPPs' Objs. and Resps. to Def.'s First Interrogs. (Jun. 14, 2017) at 13 (Response to Interrogatory No. 7).

164. The Term Sheet's Development Fee reflected a price of \$8.00 per vial.

Defendants' Evidence: Ex. 57, Ceftaroline Term Sheet, § 6.

165. When Orchid began producing validation batches, the Term Sheet contemplated that the price per vial would drop to \$3.75 per vial.

Defendants' Evidence: Ex. 57, Ceftaroline Term Sheet, § 6.

166. Further, when Orchid began producing commercial batches of ceftaroline, Forest would pay between \$3.25 and \$3.75 per vial.

Defendants' Evidence: Ex. 57, Ceftaroline Term Sheet, § 6.

167. The prices per vial contemplated by the Term Sheet all represented significant cost savings for Forest who was, at the time of the agreement, paying "over \$10 per vial" to Dobfar.

Defendants' Evidence: Ex. 324, Solomon (Sept. 7) Dep. 214:6-215:20 ("[T]he supply arrangement we made with Orchid was highly favorable to us at a much lower price than what we were then paying to Dobfar. . . . At that point we were paying over \$10 a vial to Dobfar and these guys were going to provide vials for three and a quarter. It's a great deal for us. A third of what we were paying for the competitor."); *compare* Ceftaroline Term Sheet, § 6 (showing \$8.00, \$3.75, and \$3.25 per vial prices) *with* Ex. 57, FRX-AT-03522446 at 450 (showing € 7,37 price per vial).

Public Document: X-Rates, *Historic Lookup: EUR to USD Conversion*, <http://www.x-rates.com/historical/?from=EUR&amount=1&date=2010-03-23> (showing exchange rate on March 23, 2010 to be €1,00 = \$1.35).

168. Forest also agreed to pay Orchid a consulting and service fee of \$2 million in three installments – the first \$666,666 was due upon the supply of API for the first validation batch of 350,000 vials, the second \$666,666 was due upon the supply of API for the second validation batch of 350,000 vials, and the third installment of \$666,668 was due upon the supply of API for the third batch of 350,000 vials.

Defendants' Evidence: Ex. 57, Ceftaroline Term Sheet, at 424-25 (§ 13).

Plaintiffs' Admissions: DPPs' Memo. in Opp'n to Mot. to Dismiss, Dkt. No. 69 at 24.

169. Upon execution of the agreement, Forest paid Orchid the first \$210,000 milestone payment.

Defendants' Evidence: Ex. 63, FRX-AT-04626461; Ex. 64, FRX-AT-04626465; Ex. 65, FRX-AT-04626489 (“Please find attached confirmation of Orchid Milestone paid today US210K”); Ex. 66, FRX-AT-04626476; Ex. 67, FRX-AT-04535254 (“The following milestones were paid to Orchid: \$210,000 upon execution of the agreement.”).

170. However, Orchid was ultimately unable to complete the other milestones contemplated in § 6 of the Term Sheet.

Defendants' Evidence: Ex. 67, FRX-AT-04535254 (“no vials were manufactured and API continues to be stored at Orchid”); Ex. 68, FRX-AT-04535269 at 270 (“In July 2011 Orchid’s manufacturing site was shut down for 6 months by the Indian government for issues around Orchid’s pollution control in relation to solid waste.”), at 271 (“During the development of the API process there have been a number of issues that have caused significant delays to the project timeline . . . the registration batches can not [sic] be used for future batches and a new plan will have to be developed.”); Ex. 332, Carnevale Dep. 49:3-18 (noting that Orchid was able to manufacture “the small amount that we asked them to manufacture just to see if they could manufacture it” but “when they wanted to scale it up, they were not able to do that”).

171. Because Orchid did not manufacture any of the 35,000 vials required under the second milestone in § 6, Forest paid Orchid \$210,000, or 50 percent of the contemplated milestone payment as consideration for Orchid having completed API manufacturing.

Defendants' Evidence: Ex. 67, FRX-AT-04535254 (“The following milestones were paid to Orchid: \$210,000 upon execution of the agreement, \$210,000 upon manufacturing of API for registration batches. This is 50% of the \$420,000 milestone that is associated with completion of manufacture of 35,000 vials by Orchid. While no vials were manufactured and API continues to be stored at Orchid, as an exception we paid 50% of the milestone in 2012 for completion of API manufacturing.”).

172. Forest paid Orchid for its partial performance, and did not pay Orchid the entire \$840,000 development fee contemplated in the Term Sheet, nor did it pay any of the additional consulting fees.

Defendants' Evidence: Ex. 69, Expert Report of Phillip Green (“Green Rep.”) ¶ 33 (“Because Orchid did not fully perform, Forest paid Orchid only the initial upfront[sic] payment and half of the first milestone. The payments made by Forest to Orchid evidence the pay-for-service nature of the Orchid Agreement.”); Ex. 67, FRX-AT-04535254 (“as an exception we paid 50% of the milestone in 2012 for completion of API manufacturing.”).

#### **D. The Orchid Settlement Agreement**

173. On March 23, 2010, Forest and Orchid entered a Settlement and Licensing Agreement resolving *Forest Laboratories, Inc. et al. v. Orgenus Pharma, Inc. et al.*, Civil Action No. 09-05105-MLD-DEA.

Defendants' Evidence: Ex. 32, Orchid Settlement Agreement, § 6 (titled “Released Claims”).

174. Section 13 states that the “Exhibits A through C constitutes the complete, final and exclusive agreement between the Parties with respect to the subject matter hereof and

supersedes and terminates any prior or contemporaneous agreements and/or understanding between the Parties, whether oral or in writing, relating to such subject matter. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth in this Agreement.”

Defendants’ Evidence: Ex. 32, Orchid Settlement Agreement, §13.

Undisputed Record Evidence: Ex. 334, Wilk (Orgenus) Dep. 204:3-205:25.

175. Section 1.14 of the Orchid Settlement Agreement permitted Orchid to launch three calendar months prior to the expiration of the ‘703 patent, and any extensions or pediatric exclusivity, provided that Orchid had obtained final approval from the FDA of its ANDA.

Defendants’ Evidence: Ex. 32, Orchid Settlement Agreement, §1.14.

Undisputed Record Evidence: Ex. 334, Wilk (Orgenus) Dep. 207:25-209:20.

176. In Section 2.5 of the Orchid Settlement Agreement Orchid represents that its attorney fees and costs in the action had exceeded \$2 million and Forest agreed to pay Orchid \$2 million to “defray a portion of the paid attorney fees and costs that Orchid has already expended in the action and to reflect a portion of the saved attorney fees and costs that Plaintiffs will not have to expend in the Action.”

Defendants’ Evidence: Ex. 32, Orchid Settlement Agreement, § 2.5.

Undisputed Record Evidence: Ex. 334, Wilk (Orgenus) Dep. 198:19-201:15.

177. Section 4.3(b) of the Orchid Settlement Agreement provides Orchid with the option of amending the Orchid Settlement Agreement for the terms offered to a later-settling generic, but Orchid did not exercise this option.

Defendants' Evidence: Ex. 32, Orchid Settlement Agreement, § 4.3(b).

Undisputed Record Evidence: Ex. 334, Wilk (Orgenus) Dep. 115:9-23.

178. Different teams at Forest negotiated the Orchid Settlement Agreement and the Ceftaroline Term Sheet.

Defendants' Evidence: Ex. 324, Solomon (Sept. 7) Dep. 220:9-21 (noting that while Mr. Solomon was involved in negotiating the Term Sheet, he was not involved in the “patent negotiation”); Ex. 333, Mears Dep. 144:5-146:17 (explaining that Ms. Mears put C.B. Rao of Orchid in touch with the patent team at Forest for discussions about the Namenda litigation).

179. It is undisputed that the Ceftaroline Term Sheet was a fair value, arm’s length business transaction.

Defendants' Evidence: Ex. 54, Fowdur Report ¶ 58 (“Ancillary agreements, including those signed contemporaneously with patent settlements, are not inherently suspicious, nor should they be presumed to cause anticompetitive delay. For instance, Forest also entered into a separate and contemporaneous agreement for an unrelated product when it settled the Hatch-Waxman litigation with Orchid. Plaintiffs’ experts have not opined that this agreement (or any other agreement with other generic manufacturers) were part of a reverse-payment settlement.”); Ex. 69, Green Report ¶ 34 (“Forest was looking for a second qualified supplier for ceftaroline. If Orchid was able to perform under the agreement, Forest would have access to ceftaroline at a reduced cost compared to Forest’s then supplier, Dobfar. Orchid stood to also benefit from the agreement as it would become a supplier of ceftaroline with minimum purchase quantities to be ordered by Forest. Thus, from a financial perspective, the consideration Forest agreed to pay Orchid in the Orchid Agreement constitutes fair value for the benefits and services received by Forest under the agreement.”).

Plaintiffs' Admissions: No Plaintiff expert alleges the Ceftaroline Term Sheet was not for value. Ex. 335, Elhauge (Sept. 29) Dep. 37:15-39:15 (agreeing that the Ceftaroline Term Sheet is not addressed in the Elhauge Report, he did not analyze the agreement, and was not prepared to testify about it at his deposition); Ex. 368, Elhauge (Nov. 10) Dep. 309:15-310:25; Ex. 363, Lamb (Oct. 6) Dep. 231:20-21 (“[T]he reverse payment between Forest and Mylan, as I understand, is the only reverse payment[sic] challenged to be anticompetitive by the Plaintiffs.”); *see generally* Ex. 55, Berndt Reply ¶ 1; Ex. 56, Lamb Reply ¶¶ 2-3.

**E. The Lexapro Agreement with Alphapharm**

180. On May 29, 2002, H. Lundbeck A/S (“Lundbeck”) and Forest entered the S-enantiomer License Agreement, whereby Lundbeck granted Forest a license to market Lexapro.

Defendants’ Evidence: Ex. 70, FRX-AT-04628179 at 180.

181. Forest submitted NDA 021-323 under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lexapro, and the FDA approved Forest’s NDA on August 14, 2002.

Public Document: FDA, *Application Number 21-323 Administrative Document Correspondence*, [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2002/21-323.pdf\\_Lexapro\\_Approv.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/21-323.pdf_Lexapro_Approv.pdf)

182. On October 3, 2005, Forest Laboratories Holdings Limited and Alphapharm Pty, Ltd. (“Alphapharm”) entered into a Distribution and Supply Agreement for Authorized Generic Lexapro.

Defendants’ Evidence: Ex. 71, FRX-AT-00000253, at -0273 (“Original Lexapro Agreement”).

Plaintiffs’ Admissions: DPPs’ Memo. in Opp’n to Mot. to Dismiss, Dkt. No. 69, at 24.

183. An authorized generic drug is manufactured and marketed under the same NDA as a brand drug, but is typically sold at a lower price than its brand counterpart.

Defendants’ Evidence: Ex. 72, Expert Report of Alexandra Mooney Bonelli, CFE (“Bonelli Rep.”)¶ 18 (“An AG is a drug that is manufactured and marketed under the same new drug application (“NDA”) as the original innovator drug; however, the AG drug is typically discounted (sold into the commercial market at a lower price) as compared to the innovator brand version.”).

Public Sources: DRA Final Rule, 72 Fed. Reg. 39,243, § 447.506(a) (“[A]n authorized generic drug means any drug sold, licensed, or marketed under an NDA approved by the FDA under section 505(c) of the FDCA; and marketed, sold, or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the brand drug.”);

184. Pursuant to the Original Lexapro Agreement, Forest authorized Alphapharm to exclusively market an authorized generic version of the oral tablet pharmaceutical drug Lexapro (“Generic Lexapro”), pursuant to NDA No. 21-323.

Defendants’ Evidence: Ex. 71, Original Lexapro Agreement, §§ 1.11, 1.18, 1.19, 2.1, 3.1.

Plaintiffs’ Admissions: DPPs’ Memo. in Opp’n to Mot. to Dismiss, Dkt. No. 69, at 24; DPPs’ Memo. of Law in Supp. of Mot. to Compel Prod. from Mylan, Dkt. No. 212, at 1.

185. The Original Lexapro Agreement also licensed and sublicensed the ‘712 and ‘941 Patents, and other intellectual property owned or controlled by Forest, “to Alphapharm to the extent any such Intellectual Property would otherwise be infringed” by the marketing of Generic Lexapro.

Defendants’ Evidence: Ex. 71, Original Lexapro Agreement, §§ 1.14, 2.1.

186. The authorization and licensing provisions of the Original Lexapro Agreement “shall not extend to the manufacture of Generic [Lexapro],” thus Alphapharm was not permitted to manufacture Generic Lexapro under this agreement.

Defendants’ Evidence: Ex. 71, Original Lexapro Agreement, § 2.2.

187. Forest agreed to supply Alphapharm’s requirements of Generic Lexapro for sale and distribution.

Defendants’ Evidence: Ex. 71, Original Lexapro Agreement, § 5.1.

188. Under the agreement, Alphapharm was permitted to enter “two weeks prior to the expiration of the ‘712 Patent, including all pediatric exclusivity based on such patent and any additional exclusivity allowed with respect to such patent.”

Defendants’ Evidence: Ex. 71, Original Lexapro Agreement, § 1.15(b), FRX-AT-00000253 at 255 (§ 1.15(b)).

189. Alphapharm agreed to pay Forest a 40% share of its product profit.

Defendants’ Evidence: Ex. 71, Original Lexapro Agreement, § 6.1(ii).

190. The agreement defined “product profit” as Alphapharm’s net sales less Forest’s manufacturing costs.

Defendants’ Evidence: Ex. 71, Original Lexapro Agreement, § 1.23.

191. The Original Lexapro Agreement required Alphapharm to, at its sole cost and expense, “maximize sales” of the Generic Lexapro.

Defendants’ Evidence: Ex. 71, Original Lexapro Agreement, § 9.1.

192. On September 5, 2007, the United States Court of Appeals for the Federal Circuit upheld the validity of the ‘712 Patent.

Public Sources: Forest Labs., Inc. v. Ivax Pharms., Inc., 501 F.3d 1263 (Fed. Cir. 2007); [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2009/076765s000TAltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2009/076765s000TAltr.pdf).

193. The ‘712 Patent was set to expire on March 12, 2012, which allowed Alphapharm to launch its authorized generic on February 29, 2012.

Defendants’ Evidence: Ex. 71, Original Lexapro Agreement, § 1.15(b).

Public Documents: Mylan, *Mylan Launches First Equivalent Product to Lexapro® Tablets*, <http://investor.mylan.com/releasedetail.cfm?ReleaseID=652623>.

194. Teva, the sole first-filing ANDA applicant, was permitted to enter on March 12, 2012 and was entitled to 180 days of exclusivity under the Hatch-Waxman Act.

Public Documents: FDA, Letter from Gary J. Buehler to Patricia Jaworski re: ANDA for Escitalopram Oxalate, [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2009/076765s000TAltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2009/076765s000TAltr.pdf); Teva, Teva Announces Launch of Generic Lexapro® in the United States; Awarded 180-Day Period of Marketing Exclusivity, [http://www.tevapharm.com/news/teva\\_announces\\_launch\\_of\\_generic\\_lexapro\\_in\\_the\\_united\\_states\\_awarded\\_180\\_day\\_period\\_of\\_marketing\\_exclusivity\\_03\\_12.aspx](http://www.tevapharm.com/news/teva_announces_launch_of_generic_lexapro_in_the_united_states_awarded_180_day_period_of_marketing_exclusivity_03_12.aspx).

195. The Original Lexapro Agreement had a five-year term after the launch of Generic Lexapro with automatic annual renewal.

Defendants' Evidence: Ex. 71, Original Lexapro Agreement, § 15.1.

196. Although the full term of the agreement was five years from the launch of Generic Lexapro, Alphapharm was given the right to terminate the Original Lexapro Agreement, upon 120 days prior written notice to Forest, one year following the launch of the Lexapro authorized generic.

Defendants' Evidence: Ex. 71, Original Lexapro Agreement, § 15.1.

#### **F. The Deficit Reduction Act of 2005 and the Issue of “Best Price” Liability**

197. In 1990, Congress established the Medicaid Drug Rebate Program (“MDRP”) to establish a program that required brand manufacturers to pay a rebate to the government on prescription drugs reimbursed by Medicaid.

Public Source: Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388 (1990);

Defendants' Evidence: Ex. 72, Bonelli Rep., ¶ 8.

198. The MDRP requires participating drug manufacturers to pay a rebate on those drugs for which a state's Medicaid agency has paid pharmacies to dispense the drug to Medicaid beneficiaries.

Public Source: 42 U.S.C. § 1396r-8(b)(1)(A); Medicaid Drug Rebate Program, <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/indEx.html> ("Manufacturers are then responsible for paying a rebate on those drugs for which payment was made under the state plan.");

Defendants' Evidence: Ex. 72, Bonelli Rep., ¶¶ 8, 9; Ex. 336, Bonelli Dep. 43:25-44:12 ("Q. Who purchases the drugs in the state Medicaid plans? . . . A. Pharmacies.").

199. To determine the rebate amount owed by a manufacturer, the Centers for Medicare & Medicaid Services ("CMS") calculates a per-unit rebate amount ("URA") based on a statutory formula.

Public Source: Medicaid Drug Rebate Program, <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/indEx.html> ("The Centers for Medicare & Medicaid Services' Medicaid Drug Rebate (MDR) system performs the URA calculation using the drug manufacturer's pricing. The specific methodology used is determined by law . . .");

Defendants' Evidence: Ex. 72, Bonelli Rep., ¶ 10.

200. The URA for a drug is tied to a product's "Best Price" or, "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States . . . ."

Public Source: 42 U.S.C. § 1396r-8(c)(1)(C)(i) (2012);

Defendants' Evidence: Ex. 72, Bonelli Rep., ¶¶ 15-17.

201. The URA is calculated, in part, using a brand manufacturer's commercial sales and discount data.

Public Sources: 42 U.S.C. § 1396r-8(b)(3); 42 C.F.R. § 447.510(a) & (d); Sample Medicaid Rebate Agreement § II(e), <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/samplerebateagreement.pdf>;

Defendants' Evidence: Ex. 72, Bonelli Rep., ¶¶ 15-17.

202. The Deficit Reduction Act of 2005 ("DRA"), in large part, became effective on January 1, 2007.

Defendants' Evidence: Ex. 72, Bonelli Rep., ¶ 22.

Public Source: Deficit Reduction Act of 2005, Pub. L. No. 109-171, §§ 6001-04 (amending 42 U.S.C. § 1927).

203. The Final Rule implementing the DRA (the "DRA Final Rule") became effective October 1, 2007.

Public Source: HHS & CMS, DRA Final Rule, 72 Fed. Reg. 39,142 (2007);

Defendants' Evidence: Ex. 336, Bonelli Dep. 70:19-71:3; Ex. 72, Bonelli Rep., ¶ 23.

204. Prior to the DRA, the MDRP did not specifically address the inclusion of authorized generic products in the innovator's best price calculation.

Public Source: Medicaid Drug Pricing Regulation: A Summary, <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2007-Fact-sheets-items/2007-07-06.html> ("Prior to the DRA, there were no statutory requirements specifically addressing authorized generics under the Medicaid Drug Rebate Program.");

Defendants' Evidence: Ex. 72, Bonelli Rep., ¶ 21; Ex. 73, FRX-AT-04617599, at 602 ("[The Original Lexapro Agreement] will create a new Best Price discount for branded Lexapro because the Deficit Reduction Act requires that manufacturers include sales of an authorized generic in its Best Price calculations.").

205. Prior to the DRA being effective, brand manufacturers commonly treated authorized generics as distinct from their brand counterparts for price reporting purposes and Best Price calculations.

Defendants' Evidence: Ex. 72, Bonelli Rep., ¶ 21; Ex. 74, FRX-AT-04447018 (explaining that the requirement that “internal US transfer prices need to be included in the best price (BP) calculation to Medicaid” affected two of Forest’s products); Ex. 75, FRX-AT-04447019 (PowerPoint presentation explaining the impact of the DRA on Authorized Generics).

206. The DRA amended the definition of Best Price to include the lowest price of an authorized generic drug, stating that “in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355 (c)], [Best Price] shall be inclusive of the lowest price for such authorized drug available from the manufacturer during the rebate period to any manufacturer, wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States . . . .”

Public Sources: Deficit Reduction Act of 2005 § 6003 (amending 42 U.S.C. § 1927(c)(1)(C)(ii));

Defendants' Evidence: Ex. 72, Bonelli Rep., ¶¶ 21-24, 22 n.18; Ex. 73, FRX-AT-04617599, at 602; Ex. 74, FRX-AT-04447018.

207. On January 23, 2008, in response to inquiries from manufacturers, CMS clarified that the DRA Final Rule “provides that the primary manufacturer include the best price of an authorized generic drug in its calculation of best price when the drug is being sold by the primary manufacturer to the secondary manufacturer. In accordance with this provision, we expect that the primary manufacturer report a BP which incorporates the transfer price at the time of sale to

the secondary manufacturer for the quarter in which the sale occurs, regardless of when the product is launched.”

Public Source: DRA Policy Inquiries, <https://www.cms.gov/Regulations-and-Guidance/Legislation/DeficitReductionAct/downloads/DRAPolicyInquiries.pdf>;

Defendants’ Evidence: Ex. 72, Bonelli Rep., ¶¶ 25-26.

208. Under the Original Lexapro Agreement, Forest would be considered a primary manufacturer, and Alphapharm would be considered a secondary manufacturer.

Defendants’ Evidence: Ex. 72, Bonelli Rep., ¶ 30; Ex. 71, FRX-AT-00000253; Ex. 73, FRX-AT-04617599, at 601-03.

209. The transfer price offered by a primary manufacturer to a secondary manufacturer is generally reflective of the cost to manufacture a drug.

Defendants’ Evidence: Ex. 72, Bonelli Rep., ¶ 28; Ex. 76, FRX-AT-04617480 (indicating that Mylan wanted to know Forest’s manufacturing cost for Lexapro because that “is their purchase price”).

210. Consistent with MDRP statutory, regulatory and sub-regulatory guidance, Forest’s stated policy in effect in 2010 was to include the best price of an authorized generic, which equated to the transfer price adjusted by the profit sharing/royalty amount, in Forest’s Best Price.

Defendants’ Evidence: Ex. 72, Bonelli Rep., ¶ 27; Ex. 336, Bonelli Dep. 55:8-56:12; Ex. 77, FRX-AT-04628295, at 299 (“This document is a government pricing policy/methodology document intended to document Forest Laboratories, Inc. interpretation and implementation of the applicable laws, regulations, industry standards and corporate policy in the administration of the MDRP for the reporting periods 10/1/2007 and 9/30/2010.”), at 320 (“Pursuant to DRA regulation, if Forest sells an authorized generic to another manufacturer, other than an unincorporated division, for resale, it shall include in Best Price the net price (net of royalties and profit share) to the purchasing manufacturer . . . .”);

211. Even when increased to account for a royalty payment (like the one contemplated under the Original Lexapro Agreement), a transfer price will be significantly lower than any other “price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States,” and thus would become a brand manufacturer’s best price.

Defendants’ Evidence: Ex. 72, Bonelli Rep., ¶ 28; Ex. 74, FRX-AT-04447018 (showing that under the DRA, best price for Tiazac dropped from \$1.023900 per unit to \$.098880 per unit); *see also* Ex. 73, FRX-AT-04617599 (noting that even after revising the best price estimate in Forest’s Lexapro Medicaid liability analysis to account for “the profit expected per unit from Mylan’s net sales” and increasing the transfer price to Mylan “by the amount of expected royalties,” using the transfer price as best price represented “a significant cost” to Forest).

212. Generally, the lower a manufacturer’s best price is, the higher its Medicaid Rebate liability will be.

Defendants’ Evidence: Ex. 78, FRX-AT-04617613 (“This will make the cost of the Mylan deal even pricier in the Medicaid segment. Looks like we’re at about a \$0.04-\$0.05 for a transfer price per unit, instead of \$0.13); Ex. 79, FRX-AT-04617585 (“With a lower Best Price, the Medicaid URA (Unit Rebate Amount) will increase . . .”); Ex. 72, Bonelli Rep., ¶ 29.

213. Since the DRA requires that a manufacturer include a transfer price in its best price calculation, authorized generic agreements that require a brand manufacturer to sell a drug to a third party at a transfer price result in substantially higher Medicaid rebate liability than those that do not require such a sale.

Defendants’ Evidence: Ex. 72, Bonelli Rep., ¶ 29 (“[W]hen a primary manufacturer enters into an arrangement whereby it manufacturers its innovator drug, labels it with another (secondary) manufacturer’s information and authorizes this secondary manufacturer to sell this AG version into the commercial marketplace, the financial relationship between the two parties (in the form of a transfer price increased by any profit share/royalty) must be accounted for in the innovator drug’s Best Price. This

transfer price plus royalty price would be the lowest available non-government price, would become the innovator drug's Best Price, would have the effect of dramatically lowering Best Price and would result in a dramatic increase the Medicaid rebate."); Ex. 73, FRX-AT-04617599 at 601-02; Ex. 80, FRX-AT-04617768.

214. Thus, the DRA exposed Forest to substantially more Medicaid liability under the Original Lexapro Agreement than it was exposed to when it entered the agreement in 2005.

Defendants' Evidence: Ex. 72, Bonelli Rep., ¶ 29; Ex. 73, FRX-AT-04617599 at 601-02 ("[T]he deal with Mylan to provide a generic version of escitalopram beginning in March 2012 will have significant cost implications" because "[t]his arrangement will create a new Best Price discount for branded Lexapro because the Deficit Reduction Act requires that manufacturers include sales of an authorized generic in its Best Price calculations."); Ex. 80, FRX-AT-04617768; Ex. 366, Solomon (Nov. 15) Dep. 396:18-397:19; 416:13-418:11.

#### **G. Projected Benefits of Forest Amending the Lexapro Agreement**

215. Forest performed three analyses to assess the potential benefits of amending the Original Lexapro Agreement: (1) a comparison of Forest's post-DRA Medicaid Liability under the Original Lexapro Agreement and Forest's liability pursuant to a potential amendment requiring Mylan to manufacture Generic Lexapro ("Medicaid Liability Analysis"), (2) a forecast projecting Forest's profit share revenue under the Original Lexapro Agreement and a potential amendment to that agreement ("The Lexapro Sales Forecasts"), and (3) a projection of the potential cost of goods sold savings Mylan could achieve if it manufactured Generic Lexapro ("COGS Summary").

Defendants' Evidence: Ex. 82, FRX-AT-04617597; Ex. 83, FRX-AT-04617598; Ex. 73, FRX-AT-04617599; Ex. 84, FRX-AT-04617605; Ex. 85, FRX-AT-04617606; Ex. 86, FRX-AT-04617612; Ex. 87, FRX-AT-04617623; Ex. 88, FRX-AT-04617630; Ex. 89, FRX-AT-04617640; Ex. 90, FRX-AT-04617645; Ex. 91, FRX-AT-04617664; Ex. 92, FRX-AT-04617667; Ex. 93, FRX-AT-04617668; Ex. 94, FRX-AT-04617673; Ex. 95, FRX-AT-04617674; Ex. 96, FRX-AT-04617708; Ex. 97, FRX-AT-04617712; Ex. 98, FRX-AT-04617713; Ex. 99, FRX-AT-04340635; Ex. 100, FRX-AT-04340640; Ex. 101, FRX-AT-04617748; Ex. 102, FRX-AT-04617753; Ex. 103, FRX-AT-04617764; Ex. 80,

FRX-AT-04617768; Ex. 104, FRX-AT-04617115; Ex. 127, FRX-AT-04617132; Ex. 124, FRX-AT-04617128; Ex. 314, FRX-AT-04617111; Ex. 315, FRX-AT-04617112; Ex. 105, FRX-AT-04617116; Ex. 106, FRX-AT-04617117; Ex. 107, FRX-AT-04617118; Ex. 108, FRX-AT-04340639; Ex. 109, FRX-AT-04617528; Ex. 110, FRX-AT-04617530; Ex. 111, FRX-AT-04617617; Ex. 112, FRX-AT-04617618; Ex. 113, FRX-AT-04617631; Ex. 114, FRX-AT-04617633; Ex. 115, FRX-AT-04617643; Ex. 116, FRX-AT-04617654; Ex. 117, FRX-AT-04617657; Ex. 118, FRX-AT-04617658; Ex. 119, FRX-AT-04340638.

216. Forest created these analyses to inform their negotiations with Mylan about a potential amendment to the Original Lexapro Agreement, and to assess whether such an amendment would ultimately be valuable for Forest.

Plaintiffs' Admissions: Ex. 349, Berndt Dep. 257:20-258:12 (indicating he had not seen evidence that the Lexapro Amendment analyses were shared with Forest management, but "could change [his] opinion" if such documents existed.).

Defendants' Evidence: Ex. 120, FRX-AT-04407590 (showing that the three analyses were used to prepare a Forest representative for a meeting with Mylan); Ex. 366, Solomon (Nov. 15) Dep. 422:10-424:24 ("Q. As the person negotiating the business deal with Mylan, did you believe those estimates to be reliable and to reflect the best estimates of people with knowledge about those issues? A. Yes. We would have relied on the numbers that were provided by the people within the area of expertise. That was their role and -- absolutely, we would have relied on them to know what they were talking about." Ex. 332, Carnevale Dep. 123:7-19 ("[I]n a business deal, you always do analysis to understand, you know, what you are currently receiving in sales, how the market is going to be impacted by an authorized generic and the business deal itself. You try to lay out here as best as you can, making some key assumptions about, you know, the money that's going to be -- that you are going to make on the deal and whether it is valuable to you."); Ex. 69, Green Rep., ¶¶ 48-49 (analyzing Forest's analyses undertaken during the Lexapro Amendment negotiations); Ex. 338, Green Dep. 98:12-20 (indicating there were a "variety of different forecasts that were prepared in early 2010 by Forest").

217. None of Plaintiffs' experts take issue with Mr. Green's application of a Net Present Value analysis to Forest's expected benefits to generate Forest's net expected value from the Amendment to Distribution and Supply Agreement (Generic Lexapro) ("Lexapro Amendment").

Plaintiffs' Admissions: Ex. 368, Elhauge (Nov. 10) Dep. 288:10-18 (indicating Prof. Elhauge used same net present value analysis as Mr. Green to determine Forest's Best Price savings); Ex. 121, Revised Expert Report of Professor Einer Elhauge ("Elhauge Rep. I"), ¶ 11 (indicating Professor Elhauge used a 10% discount rate, the same rate as used by Mr. Green, to calculate the size of the alleged reverse payment); Ex. 122, Rebuttal Expert Report of Professor Einer Elhauge ("Elhauge Rep. II"), ¶ 23 (acknowledging, and not disputing, Mr. Green's new present value analysis as applied to Forest's Medicaid savings); Ex. 337, Bruno Dep. 163:14-20 ("Q. And you're not using standards from the FASB (Financial Accounting Standards Board), correct? A. I'm not using the typical accounting standards that you want to apply.").

**i. Forest's Projected Savings from Shifting Manufacturing of the Lexapro Authorized Generic to Mylan**

218. Mylan acquired Alphapharm in 2007.

Public Source: Mylan in Australia, MYLAN, <http://www.mylan.com.au/en-au/company/mylan-in-australia> (last visited October 7, 2017).

219. On July 21, 2009 Mylan approached Forest to obtain the information necessary to model expectations for the authorized generic product under the Original Lexapro Agreement.

Defendants' Evidence: Ex. 76, FRX-AT-04617480 ("I received a call from a gentlemen at Mylan today . . . who was referred to me by Charles Ryan. He is trying to model expectations for the authorized generic product under the Distribution Right Agreement with Alphapharm for Lexapro and wanted to know our cost of manufacture (which is their purchase price)").

220. By July 22, 2009, and in conjunction with Forest's internal discussions about the cost implications of the DRA's effect on Medicaid best price, Forest decided to approach Mylan to discuss a possible adjustment to the Original Lexapro Agreement.

Defendants' Evidence: Ex. 76, FRX-AT-04617480 ("You should let [Mylan] know that we would like to have a meeting in the fall to discuss a possible adjustment to the deal structure. In addition to understanding the legal aspect, we should look at the potential cost of the best price issue."); Ex. 324, Solomon (Sept. 7) Dep. 103:14-106:24 ("So we had an original agreement with Alphapharm, which was now Mylan, under which we were meant to supply the product to Mylan for them to sell the authorized generic. And

we recognized that based on that existing supply arrangement we would wind up with a very significant liability due to the best price issue, and so we wanted to change that – that supply arrangement, so that we were not supplying Mylan.”); Ex. 366, Solomon (Nov. 15) Dep. 396:18-397:19 (“So, we had identified that was an issue that we needed to address. We had identified it before any discussion of a settlement with Mylan arose, and it was an issue that we needed to address.”).

221. In January 2010, Forest began to compare the additional Medicaid rebate liability it would incur under the Original Lexapro Agreement, by manufacturing an authorized generic version of Lexapro for Mylan’s distribution and sale (“Scenario 1”), with the Medicaid rebate liability Forest would incur under a possible amendment, whereby Mylan manufactured the authorized generic version of Lexapro for its own distribution and sale (“Scenario 2”).

Defendants’ Declaration: Ex. 123, Declaration of James Finchen (“Finchen Decl.”) (Oct. 3, 2017) ¶¶ 7-8; Ex. 73, FRX-AT-04617599 (“Scenario 1 – Sell to Mylan”; “Scenario 2 – no transfer price”); Ex. 84, FRX-AT-04617605.

222. Forest analyzed the DRA’s effect on Lexapro’s best price and concluded that, under the Original Lexapro Agreement, the transfer price that Mylan would pay Forest for manufacturing authorized generic escitalopram would be “much lower” than the 2010 best price, (which was “only a 20% discount to WAC”), even after increasing the transfer price to account for Forest’s profit share under an amendment.

Defendants’ Evidence: Ex. 73, FRX-AT-04617599, at 602; Ex. 80, FRX-AT-04617768 (Forest’s March 2010 Medicaid Liability Analysis shows Forest estimated Best Price to be \$0.57, or an 82.8% discount to WAC in Q1 2012); Ex. 103, FRX-AT-04617764 (concluding that with a graduate profit share, “[t]he adjustments to the profit share arrangement result in a lower best price in the initial quarters of the deal because Forest’s profit share of each unit that Mylan sells is now lower, and this is a component of the transfer price.”); Ex. 78, FRX-AT-04617613 (Forest analyzed how the transfer price to Mylan might affect its Medicaid Liability, “This will make the cost of the Mylan deal even pricier in the Medicaid segment. Looks like we’re at about a \$0.04-\$0.05 for a transfer price per unit, instead of \$0.13.”).

223. Forest expected that the significantly lower Best Price contemplated under the DRA would greatly increase the Medicaid URA for Lexapro.

Defendants' Evidence: Ex. 73, FRX-AT-04617599 at 602 ("As a consequence of this significantly lower Best Price, the statutory Medicaid URA (Unit Rebate Amount) will increase beyond the point where we have to pay a URA that exceeds the WAC."); Ex. 78, FRX-AT-04617613 ("This will make the cost of the Mylan deal even pricier in the Medicaid segment. Looks like we're at about a \$0.04-\$0.05 for a transfer price per unit, instead of \$0.13.").

224. Forest believed that the significantly lower Best Price may lead to as much as \$75 million in additional Best Price liability.

Defendants' Evidence: Ex. 366, Solomon (Nov. 15) Dep. 416:13-418:11 ("And I recall that at some point numbers as high as 70 to 75 [million] were invoked.").

225. Various groups at Forest that specialized in particular areas provided key assumptions and inputs that were incorporated into the Medicaid rebate liability forecast.

Defendants' Declaration: Ex. 123, Finchen Decl. ¶ 13; Ex. 332, Carnevale Dep. 106:15-24, 117:8-24, 196:1-19, 198:1-8; Ex. 75, FRX-AT-04447019 (PowerPoint presentation explaining the impact of the DRA on Authorized Generics).

226. The assumptions incorporated in the Medicaid rebate liability analyses were based upon Forest's experience in the industry and reasonable expectations at the time of the analysis, and included: (1) Lexapro financial planning and analysis forecasts, which included projected Lexapro utilization and projected Lexapro pricing; (2) expected commercial contracting discounts for Lexapro (which impacts the Lexapro best price discount); (3) expected Generic Lexapro launch date of March 2012; (4) Forest's expected costs of goods sold; (5) calculations of expected profit share payments from Mylan to Forest (for all forecasts post-dating January 14, 2010) which were calculated as part of the Lexapro Generic Analysis Forecast provided by

Robert Carnevale; and (6) expected quarterly change in customer price index, a component of the best-price calculation.

Defendants' Declaration: Ex. 123, Finchen Decl. ¶ 13; Ex. 366, Solomon (Nov. 15) Dep. 422:10-424:24.

227. In each case, Forest estimated that it would save at least \$20 million in Medicaid rebate liability under Scenario 2 as compared to Scenario 1.

Defendants' Declaration: Ex. 123, Finchen Decl. ¶ 14; Ex. 366, Solomon (Nov. 15) Dep. 416:13-418:11.

228. Since the Scenario 1 transfer price to Mylan would reflect the lowest price Forest offered to a commercial customer during the first quarter of 2012, it would be considered the Best Price for the entire quarter, even though that price was not available until February.

Defendants' Evidence: Ex. 72, Bonelli Rep., ¶ 17 (“In general, Best Price reflects the lowest price available from a manufacturer to any commercial customer in the United States within an individual calendar quarter, even if that price was not available for the duration of the quarter.”).

229. Therefore, the reduction in Medicaid liability between Scenario 1 and Scenario 2 is the largest in the first quarter of 2012 because the transfer price offered to Mylan in February 2012 would be applied to the entire pre-loss-of-exclusivity-volume of brand Lexapro sales to Medicaid patients.

Defendants' Evidence: Ex. 72, Bonelli Rep. ¶ 17; Ex. 73, FRX-AT-04617599 at 603 (“[B]ecause the manufacturing agreement is slated to begin two weeks prior to LOE of Lexapro (*i.e.*, in late February/early March 2012), the combination of higher Medicaid sales (because the brand share of the generic + brand total will still be high) and the very low Best Price during Q1 CY2012 will cause most of the liability resulting from this deal to occur that quarter.”); Ex. 80, FRX-AT-04617768 (March 2010 Medicaid Liability

Forecast predicts more than \$18,000,000 of the total \$30,437,000 in savings will be realized in the first quarter of 2012).

230. Because Forest pays reimbursement to Medicaid for Medicaid patients' purchase of brand-Lexapro only (under Scenario 1 or Scenario 2), the potential Medicaid liability savings Forest predicted declines after the first quarter of 2012 because Forest expected brand Lexapro to lose sales to generic entrants.

Defendants' Evidence: Ex. 80, FRX-AT-04617768.

231. Ultimately, Forest's analysis estimated that, over nine quarters, Forest would owe \$60,458,000 under Scenario 1 compared to \$30,021,000 under Scenario 2.

Defendants' Evidence: Ex. 80, FRX-AT-04617768.

232. Thus, Forest expected that it would save \$30,437,000, over nine quarters, (\$18,363,000 of which would be saved in the first quarter alone, and \$26,467,000 of which would be saved over the first five quarters), if it amended the Original Lexapro Agreement to require Mylan to manufacture Generic Lexapro.

Defendants' Evidence: Ex. 80, FRX-AT-04617768; Ex. 123, Finchen Decl. ¶ 15; Ex. 69, Green Rep., ¶¶ 73-74.

233. Plaintiffs' expert James Bruno conceded that in order to reduce the Medicaid best price liabilities someone other than Forest had to manufacture the Generic Lexapro.

Plaintiffs' Admissions: Ex. 337, Bruno Dep. 336:13-337:2 ("Q. You understand that in order to reduce the Medicaid best price liabilities, someone other than Forest had to manufacture the authorized generic for Lexapro, correct? . . . A. I understand that for Forest there would have been an interest to move the manufacturing out of a Forest manufacturing facility. Q. Into someone that isn't Forest to manufacture the drug, right? A. Correct. A non-Forest facility is what I said.").

234. Plaintiffs' expert James Bruno did not dispute whether the amount that Forest would save in Medicaid best price liabilities was reasonable at the time Forest calculated it.

Plaintiffs' Admissions: Ex. 337, Bruno Dep. 339:14-340:11 ("Q. Again, you are not disputing whether the \$26.5 million figure that Mr. Green relies on his report, you aren't disputing whether that future was reasonable at the time that Forest estimated it, correct? A. To the best of my knowledge, that number and how he calculated it, I didn't dispute the number.").

235. None of Plaintiffs' experts dispute that Forest's expectation was that it was going to receive \$26.5 million in Medicaid savings from the Lexapro Amendment.

Plaintiffs' Admissions: Ex. 337, Bruno Dep. 337:15-22 (indicating he is not disputing Forest's expectation to receive the benefit of lower Medicaid liability under the Lexapro Amendment); Ex. 368, Elhauge (Nov. 10) Dep. 262:1-9 (agreeing that the effect of moving manufacturing responsibilities to Mylan was to lower Forest's Medicaid payments); Ex. 122, Elhauge Rep. II, ¶ 22-23 (agreeing the Lexapro Agreement resulted in lower Medicaid liability to Forest).

**ii. Forest's Projected Earnings Under a Possible Lexapro Amendment with Mylan**

236. Prior to executing the Lexapro Amendment, Forest prepared several analyses that forecasted the financial impact of potentially amending the Original Lexapro Agreement in three important ways: (1) amending the fixed 40% profit share to a graduated scale, providing for Forest's share of product profit to be 30% as to the first \$100 million of cumulative product profit, 35% with respect to the next \$50 million in cumulative product profit, and 40% with respect to cumulative product profit in excess of \$150 million; (2) extending the minimum term of the Original Lexapro Agreement from one to two years; and (3) shifting manufacturing responsibilities to Mylan.

Defendants' Evidence: Ex. 104, FRX-AT-04617115; Ex. 127, FRX-AT-04617132; Ex. 124, FRX-AT-04617128; Ex. 314, FRX-AT-04617111; Ex. 315, FRX-AT-04617112; Ex. 105 FRX-AT-04617116; Ex. 106, FRX-AT-04617117; Ex. 107 FRX-AT-04617118; Ex. 99, FRX-AT-04340635; Ex. 108, FRX-AT-04340639; Ex. 109, FRX-AT-04617528; Ex. 110, FRX-AT-04617530; Ex. 111, FRX-AT-04617617; Ex. 112, FRX-AT-04617618; Ex. 113, FRX-AT-04617631; Ex. 114, FRX-AT-04617633; Ex. 89, FRX-AT-04617640; Ex. 115, FRX-AT-04617643; Ex. 116, FRX-AT-04617654; Ex. 117, FRX-AT-04617657; Ex. 118, FRX-AT-04617658.

237. Robert Carnevale, a member of Forest's Alliance Management Group, prepared several analyses forecasting Forest's potential earnings under the Original Lexapro Agreement as well as the contemplated Lexapro Amendment the input of several other Forest employees.

Defendants' Evidence: Ex. 332, Carnevale Dep. 9:8-10:3, 110:17-113:15, 116:25-117:24, 119:6-13, 122:22-125:14 (noting that between January and when the Lexapro Amendment was actually signed, there were multiple analyses done to assess whether an amendment would be valuable to Forest and that several different groups decided which assumptions should be incorporated in the Lexapro Sales Forecasts).

238. There is no evidence in the record suggesting that Forest's projections for either the profit share or the best price savings are a sham.

Defendants' Evidence: Ex. 338, Green Dep. 249:18-250:12.

Plaintiffs' Admission: Ex. 349, Berndt Dep. 279:7-15.

**a. Impact of Amending the Fixed 40% Profit Share to a Graduate Profit Share Scale**

239. Forest expected that, under a potential Lexapro Amendment, Generic Lexapro cumulative product profits would total \$429.4 million in the first full year after launch, and Forest's profit share would be \$159.2 million.

Defendants' Evidence: Ex. 104, FRX-AT-04617115; Ex. 127, FRX-AT-04617132; Ex. 69, Green Rep., ¶ 50.

240. Notably, Forest expected that from March 2012 to May 2012, the cumulative product profit would be \$172.9 million, and thus expected to receive a 40% profit share just a few months after the launch of Generic Lexapro.

Defendants' Evidence: Ex. 104, FRX-AT-04617115; Ex. 127, FRX-AT-04617132; Ex. 69, Green Rep., ¶ 50.

241. Assuming, as Forest expected, that the \$150 million product profit threshold would be reached, the Lexapro Amendment would require Forest to be paid a 35% profit share instead of a 40% share, which represents a \$2.5 million reduction in Forest's expected profit share payments.

Defendants' Evidence: Ex. 69, Green Rep. at ¶¶ 51-52.

242. Assuming, as Forest expected, that the \$100 million threshold would be reached, the Lexapro Amendment would require Forest to be paid a 30% profit share instead of a 40% share, which represents a \$10 million reduction in Forest's expected profit share payments.

Defendants' Evidence: Ex. 69, Green Rep. at ¶¶ 51-52.

243. Thus, an amendment to the Original Lexapro Agreement that changed the profit share percentage payable to Forest from a fixed 40% to the graduated scheme described above represented a maximum reduction of Forest's profit share payments of \$12.5 million.

Defendants' Evidence: Ex. 69, Green Report at ¶¶ 52-53.

244. Any product profits exceeding \$150 million would be subject to the same 40% profit share percentages contemplated under the Original Lexapro Agreement, so the change in profit share percentage would not affect those revenues.

Defendants' Evidence: Ex. 69, Green Report at ¶¶ 51-52.

**b. Impact of Extending The Minimum Term Of The Original Lexapro Agreement From One To Two Years**

245. Despite the fact that an adjustment to the profit share payments would potentially decrease Forest's profits under an amended agreement, Forest expected that the extension of the minimum term of the agreement from one to two years represented the opportunity to offset the reduction of the profit share income.

Defendants' Evidence: Ex. 324, Solomon (Sept. 7) Dep. 100:10-101:3, 103:14-106:24; Ex. 366, Solomon (Nov. 15) Dep. 424:25-426-21; Ex. 69, Green Rep. ¶¶ 55, 59 (indicating Forest expected to gain \$21.1 million in net profit share from a second year extension, which is greater than the \$12.5 million from the reduced profit share percentages); Ex. 338, Green Dep. 76:2-13 ("Q. Okay. So you are saying the 12 and a half million dollar reduced payment that Forest would receive in year one would be offset by the expected profit-share payments in year two? A. Yes. In doing any analysis of fairness, one would take a look at the expectations of the parties at the time the deal was done, and at the time Forest's projections indicated that it was expecting to have profit-share payments in the second year that would offset the reduced profit-share payments in the first."); Ex. 104, FRX-AT-04617115; Ex. 127, FRX-AT-04617132.

246. Forest expected that under the Original Lexapro Agreement, Alphapharm/Mylan would have terminated the agreement as soon as the one-year minimum term expired.

Defendants' Evidence: Ex. 324, Solomon (Sept. 7) Dep. 103:14-106:24 ("Mylan's leverage as a large well established American generic company getting a head start being able to get a big share, we felt that they were likely after the one-year expiration of the original license to substitute their own product instead of continuing to sell ours and we would lose our share of the value of the generic after that. And we wanted to extend that for an additional period of time."); Ex. 366, Solomon (Nov. 15) Dep. 424:25-426-21; Ex. 108, FRX-AT-04340639 (iteration of Lexapro Generic Analysis forecasting only one year of authorized generic sales); Ex. 112, FRX-AT-04617618 (same); Ex. 115, FRX-AT-04617643 (same); Ex. 118, FRX-AT-04617658 (same).

247. Since Mylan could sell its own generic escitalopram product after Forest's patent expired in 2012 and avoid paying Forest a profit share, it would be financially and economically

rational for Mylan to cease selling Generic Lexapro under the Original Lexapro Agreement at the end of a year.

Defendants' Evidence: Ex. 366, Solomon (Nov. 15) Dep. 424:25-426-21; Ex. 69, Green Rep. ¶ 55; Ex. 54, Fowdur Rep. ¶ 50; Ex. 338, Green Dep. 100:8-101:21 (“Q. Okay. But the profit sharing in the original agreement continued throughout the term of the agreement? It wasn’t just for the first year? A. To the extent that Mylan continued in the agreement, . . . my understanding is that they would have been obligated to continue to make payments after year one. However, the original agreement allowed Mylan to exit the agreement after year one, and it would have been financially rational for them to do that, because they wouldn’t have to make the profit sharing payments.”); Ex. 324, Solomon (Sept. 7) Dep. 103:14-106:24 (“Mylan’s leverage as a large well established American generic company getting a head start being able to get a big share, we felt that they were likely after the one-year expiration of the original license to substitute their own product instead of continuing to sell ours and we would lose our share of the value of the generic after that. And we wanted to extend that for an additional period of time.”).

248. If the minimum term of the Original Lexapro Agreement were extended by a year, Forest forecasted that the total product profits in the second year of the term would be \$79.3 million, and that Forest would earn \$21.1 million in net profit share (after paying a profit share to Lundbeck).

Defendants' Evidence: Ex. 104, FRX-AT-04617115; Ex. 127, FRX-AT-04617132; Ex. 69, Green Rep. ¶¶ 57-59.

249. Because Forest expected Mylan to terminate the Original Lexapro Agreement after one year, Forest considered these increased profits to be all incremental and the result of the Lexapro Amendment.

Defendants' Evidence: Ex. 324, Solomon (Sept. 7) Dep. 103:14-106:24 (“The second issue was that given that Mylan was a much more substantial generic company following the acquisition of Alphapharm than Alphapharm was by itself, we felt that the value of that authorized generic would be meaningful and under the terms of our supply arrangement with Mylan, the license with Mylan, Mylan would be the first one to enter the market with a two-week head start and what that would mean is they ought to be able to get a large share of the generic Lexapro market and so our view – and typically once a

company gets the share, suppliers won't change unless they have a reason to change. And so with Mylan's leverage as a large well established American generic company getting a head start being able to get a big share, we felt that they were likely after the one-year expiration of the original license to substitute their own product instead of continuing to sell ours and we would lose our share of the value of the generic after that.").

250. The combined impact of the reduced profit share and the extension of the minimum term of the Original Lexapro Agreement would result in at least an additional \$8.6 million in net benefits for Forest (\$21.1 million in increased profit share for year two, less \$12.5 million in lower profit share payments due to the graduated profit share).

Defendants' Evidence: Ex. 69, Green Rep. ¶ 65.

251. Plaintiffs' expert James Bruno conceded that a risk-averse company would want to have a minimum term on which they are receiving payments related to an agreement.

Plaintiffs' Admissions: Ex. 337, Bruno Dep. 240:25-241:9 ("Q. You said a few moments ago, though, that if a company were risk-averse and wanted a guarantee, that it would make sense for them to pay to extend the minimum term, correct? A. It would make sense for them to have a minimum term on which they are receiving payment, they received the royalty payment, that's the payment.")

252. The addition of a second year of profit sharing after reduction of a first year's profit split is a commercially reasonable method for the parties to share the risk of entry by other generic manufacturers as well as changes to the Lexapro market.

Defendants' Evidence: Ex. 338, Green Dep. 131:20-132:19.

**c. Impact of Shifting Manufacturing Costs to Mylan**

253. Forest also projected that Mylan would achieve manufacturing cost savings, and those cost savings would make Generic Lexapro more profitable overall, increasing the profit share income for both parties.

Defendants' Evidence: Ex. 124, FRX-AT-04617128 (projected total Mylan cost of goods sold savings to be \$2.56 million in the first year of authorized generic sales); Ex. 324, Solomon (Sept. 7) Dep. 360:11-362:1 (“Mylan was a much larger manufacturer. They produced far, far more pills and SKUs and had huge industrial production, much larger than we did at Forest, and so we understood that Mylan could produce the product more cost effectively than we could so the thinking was there were probably several million dollars in additional profit that would come, you know, that would it be there for sharing because Mylan could do it more cost effectively, and that was something that again we had modeled and I think was in one of these documents here but it was just the scale of production for a company like Mylan with hundreds and hundreds of products and thousands of SKUs and huge, you know, manufacturing infrastructure. They just have an economy of scale that Forest could never achieve so their ability to produce it more cost effectively would mean the amount of profit that was available for sharing of which we got our piece would be – would be greater.”); Ex. 69, Green Report ¶ 54.

254. On its March 2010 forecasts, Forest used its own cost of goods, and not Mylan’s expected lower costs, to project the profit share they would receive from Mylan under the Amendment Lexapro Amendment.

Defendants' Evidence: Ex. 125, FRX-AT-04617114 (Key Assumption 7 identifying Forest’s Cost of Goods Sold as an input); Ex. 104, FRX-AT-04617115 (same); Ex. 69, Green Rep. ¶¶ 49, 61.

Plaintiffs' Admissions: Ex. 337, Bruno Dep. 280:6-20, 295:6-22 (“Q. . . . at any point in your reports did you say that the 0.0596 cost of goods sold figure for Forest was inaccurate? . . . A. I didn’t say it was accurate, nor did I say it was inaccurate. I said it was equivalent to what Mylan cost of goods would be. Q. And that’s the cost of goods sold that Forest used to project what its royalty payments were going to be under the 2010 Lexapro Amendment, correct? A. Based on this chart, it would look like that’s the number they assumed was the cost of goods.”).

**H. The Lexapro Amendment with Mylan**

255. On July 21, 2010 Forest and Mylan executed the Lexapro Amendment.

Defendants' Evidence: Ex. 126, FRX-AT-00000464.

256. Alphapharm, the original counterparty to the Original Lexapro Agreement, appointed Mylan as its assignee.

Defendants' Evidence: Ex. 126, FRX-AT-00000464.

257. Whereas the Original Lexapro Agreement required Forest to manufacturer and supply Mylan's requirements of Generic Lexapro, the Lexapro Amendment authorized Mylan to manufacture its own requirements of Generic Lexapro

Defendants' Evidence: Ex. 71, FRX-AT-00000253, at 259-260 (§ 5.1); Ex. 126, FRX-AT-00000464, at 466-70 (§§ 4-5)

258. The Lexapro Amendment required Mylan to qualify an appropriate facility to manufacture Mylan's requirements of Generic Lexapro, and for Mylan to incur the costs of the qualification.

Defendants' Evidence: Ex. 126, FRX-AT-00000464 at 467-70 (§ 5).

259. In turn, Forest agreed to provide "technology transfer assistance as Mylan may reasonably request to assure a smooth, efficient and timely transfer of any technology related to [Generic Lexapro] . . . ."

Defendants' Evidence: Ex. 126, FRX-AT-00000464 at 468 (§ 5).

260. “In consideration for the amendments and modifications to the [Original Lexapro Agreement] . . . and for the undertakings of Mylan with respect to Manufacturing of [Generic Lexapro], Forest agree[d] to pay Mylan US \$20 million . . . .”

Defendants’ Evidence: Ex. 126, FRX-AT-00000464 at 470 (§ 6.1).

261. The Lexapro Amendment altered the definition of “Manufacturing Costs” to be Mylan’s direct costs of manufacture, packaging, testing, validation and shipping of authorized Generic Lexapro.

Defendants’ Evidence: Ex. 126, FRX-AT-00000464 at 466 (§ 1.16).

262. By modifying the definition of Manufacturing Costs, the Lexapro Amendment also modified the definition of “Product Profit” as set forth in the Original Lexapro Agreement to be Mylan’s “net sales” less Mylan’s manufacturing costs (versus Mylan’s net sales less Forest’s manufacturing costs under the original agreement).

Defendants Documents: Ex. 126, FRX-AT-00000464 at 466 (§ 1.16, redefining Manufacturing Costs); Ex. 71, FRX-AT-00000253 (§ 1.23 defining Product Profit as net sales less “the Manufacturing Costs for [Generic Lexapro]”).

263. Mylan agreed to pay Forest a profit share of 30% as to the first \$100 million of cumulative product profit, 35% with respect to the next \$50 million in cumulative product profit and 40% with respect to cumulative product profit in excess of \$150 million.

Defendants’ Evidence: Ex. 126, FRX-AT-00000464 at 466, 470-471 (§ 6); Ex. 69, Green Rep. ¶ 45.

264. The Original Lexapro Agreement was also amended to permit Mylan to terminate the Lexapro Amendment two years following the launch of Generic Lexapro, as opposed to one

year following the launch of Generic Lexapro as permitted under the Original Lexapro Agreement.

Defendants' Evidence: Ex. 126, FRX-AT-00000464 at 472 (§11).

265. In accordance with its analyses, under the Lexapro Amendment, Forest incurred \$20 million of liability to Mylan by agreeing to pay it a lump sum, and reduced its profit share payments by \$12.5 million under the graduated profit share amendment, but extended the minimum term of the agreement to achieve its expected \$21.1 million of additional profit share revenue in year two, and shifted the manufacturing responsibilities to Mylan for an expected \$26.5 million savings in year one Medicaid rebate liability.

Defendants' Evidence: Ex. 324, Solomon (Sept. 7) Dep. 100:10-101:3, 103:14-106:24; Ex. 69, Green Rep. ¶¶ 55, 59; Ex. 338, Green Dep. 76:2-13 (“Q. Okay. So you are saying the 12 and a half million dollar reduced payment that Forest would receive in year one would be offset by the expected profit-share payments in year two? A. Yes. In doing any analysis of fairness, one would take a look at the expectations of the parties at the time the deal was done, and at the time Forest's projections indicated that it was expecting to have profit-share payments in the second year that would offset the reduced profit-share payments in the first.”); Ex. 104, FRX-AT-04617115; Ex. 127, FRX-AT-04617132; Ex. 366, Solomon (Nov. 15) Dep. 415:5-416:2.

266. Mylan received a \$20 million lump sum payment, saved \$12.5 million dollars on the first \$150 million of profit share payments to Forest, and agreed to extend the minimum term of the agreement to pay Forest its profit share for at least one additional year (which Forest expected would cost Mylan \$31.7 million).

Defendants' Evidence: Ex. 69, Green Rep. ¶ 46, 52-53, 59, 75; Ex. 126, FRX-AT-00000464, at 470 (§ 6); Ex. 104, FRX-AT-04617115; Ex. 127, FRX-AT-04617132; Ex. 366, Solomon (Nov. 15) Dep. 415:5-416:2.

## **I. Mylan's Threatened Antitrust Suit**

267. On February 19, 2010, Mylan sent Forest a draft complaint that alleged Forest engaged in antitrust violations.

Defendants' Evidence: Ex. 128, FRX-AT-03629657; Ex. 129, FRX-AT-03629662.

268. The draft complaint alleged antitrust violations in connection with Forest's application for a Patent Term Extension with the United States Patent and Trademark Office for U.S. Patent No. 5,061,703, listed in the Orange Book for Namenda.

Defendants' Evidence: Ex. 130, FRX-AT-03629684; Ex. 129, FRX-AT-03629662, at 663; Ex. 340, Agovino Dep. 102:19-25;

Undisputed Record Evidence: Ex. 329, Silber (Mylan) Dep. 68:18-25.

269. Mylan shared the draft antitrust complaint with Forest after the parties executed a standstill agreement on February 18, 2010 with respect to Mylan's antitrust allegations, whereby Forest agreed to not take any action that would prejudice or delay Mylan's ability to file the antitrust complaint, and Mylan agreed to file the antitrust complaint no sooner than February 26, 2010, so that the parties had an opportunity to settle the allegations prior to the filing of the complaint.

Defendants' Evidence: Ex. 131, FRX-AT-03629651; Ex. 132, FRX-AT-03629655; Ex. 128, FRX-AT-03629657; Ex. 324, Solomon (Sept. 7) Dep. 305:18-306:23, 309:15-23;

Undisputed Record Evidence: Ex. 329, Silber (Mylan) Dep. 63:1-14, 64:21-66:5.

270. Mylan's antitrust complaint, if filed and successful, could have exposed Forest to hundreds of millions of dollars of damages and the cost of defending a complex antitrust suit.

Defendants' Evidence: Ex. 129, FRX-AT-03629662 at 9682 (including in its Prayer for Relief a claim for “damages, costs of suit, interest and attorneys fees . . .”);

Defendants' Evidence: Ex. 324, Solomon (Sept. 7) Dep. 316:2-21; Ex. 341, Fowdur Dep. 77:15-79:20; Ex. 54, Fowdur Rep. ¶¶ 55-56;

Undisputed Record Evidence: Ex. 329, Silber (Mylan) Dep. 19:1-17, 20:13-24, 22:8-14.

271. Mylan released its potential antitrust claims at the same time Forest and Mylan entered into the Namenda patent settlement agreement and Lexapro Amendment.

Defendants' Evidence: Ex. 33, FRX-AT-00000428 at 0429-0430 (releasing “all claims that Mylan . . . could have asserted . . . in any judicial proceeding that the ‘703 Patent, or any patent term extension related thereto . . . is somehow invalid, unenforceable or not infringed . . .”);

Defendants' Evidence: Ex. 324, Solomon (Sept. 7) Dep. 143:19-144:6; Ex. 340, Agovino Dep. 131:19-22, 132:22-134:3;

Third Party Evidence: Ex. 329, Silber (Mylan) Dep. 20:25-21:2, 21:5-11 (indicating Mylan released its potential antitrust claims in connection with the Namenda patent settlement agreement).

272. Mylan released the allegations made in the draft antitrust complaint in its Namenda patent settlement agreement with Forest.

Defendants' Evidence: Ex. 33, FRX-AT-00000428 at 429-430 (§ 6) (releasing “all claims that Mylan . . . could have asserted . . . in any judicial proceeding that the ‘703 Patent, or any patent term extension related thereto . . . is somehow invalid, unenforceable or not infringed . . .”); Ex. 324, Solomon (Sept. 7) Dep. 142:23-144:6;

Undisputed Record Evidence: Ex. 329, Silber (Mylan) Dep. 21:5-22:7.

273. Mylan believed a portion of the consideration paid to Mylan in connection with the Lexapro Amendment was in consideration for Mylan releasing its antitrust allegations against Forest.

Undisputed Record Evidence: Ex. 329, Silber (Mylan) Dep. 84:4-10.

**J. The Mylan Settlement Agreement**

274. On July 21, 2010, Forest and Mylan entered into a Settlement and Licensing Agreement (“Mylan Settlement Agreement”) resolving *Forest Laboratories, Inc. et al. v. Lupin Pharmaceuticals, Inc. et al.*, Civil Action No. 08-021-GMS-LPS (consolidated) in the United States District Court for the District of Delaware.

Defendants’ Evidence: Ex. 33, FRX-AT-00000428.

275. The Mylan Settlement Agreement was negotiated by a different team of Forest employees than those that negotiated the Original Lexapro Agreement and the Lexapro Amendment.

Defendants’ Evidence: Ex. 324, Solomon (Sept. 7) Dep. 95:5-96:8 (noting that Mr. Solomon was not involved in the negotiation of the patent settlement agreement because that was handled by, Charles Ryan and Eric Agovino, Forest’s patent counsel); Ex. 339, Ryan (Sept. 7) Dep. 235:15-24 (indicating David Solomon, Rachel Mears, and Robert Carnevale had no role in negotiating the settlement agreements with the generic manufacturers).

276. Section 13 of the Settlement Agreement states that “Exhibits A through C, constitutes the complete, final and exclusive agreement between the Parties with respect to the subject matter hereof and supersedes and terminates any prior or contemporaneous agreements and/or understandings between the Parties, whether oral or in writing, relating to such subject matter.”

Defendants’ Evidence: Ex. 33, FRX-AT-00000428, at 434 (§ 13).

277. Section 1.13 of the Mylan Settlement Agreement permitted Mylan to launch three calendar months prior to the expiration of the ‘703 patent, and any extensions or pediatric exclusivity, provided that Mylan had obtained final approval from the FDA of its ANDA.

Defendants’ Evidence: Ex. 33, FRX-AT-00000428 at 447;

Undisputed Record Evidence: Ex. 329, Silber (Mylan) Dep. 22:17-23:4.

278. In Section 2.5 of the License Agreement, included as Exhibit B to the Mylan Settlement Agreement, Mylan represented that its attorney fees and costs in the action had exceeded \$2 million, and Forest agreed to pay Mylan \$2 million to “defray a portion of the paid attorney fees and costs that Mylan has already expended in the Action and to reflect a portion of the saved attorney fees and costs that Plaintiffs will not have to expend in the Action . . . .”

Defendants’ Evidence: Ex. 33, FRX-AT-00000428 at 449 (§ 2.5).

279. The terms of the settlement had been agreed in principle in early 2010, while Forest’s business development teams continued to negotiate the terms of the Lexapro Amendment.

Defendants’ Evidence: Ex. 329, Silber (Mylan) Dep. 26:12-27:5, 61:16-24, 73:10-21, 81:5-14.

280. Forest estimated that, at the time of the Mylan Settlement Agreement, Forest’s future litigation costs were in the “high single digit millions” and up to \$10 million.

Defendants’ Evidence: Ex. 325, Snyder Dep. 29:7-15; Ex. 324, Solomon (Sept. 7) Dep. 236:2-237:24 (“My understanding is our internal projections were we had, you know, probably another 10 million dollars of legal expenses and associated costs left.”).

### III. GENERIC SETTLEMENTS: NO CAUSATION

#### A. The Namenda IR Patent Litigation Against Fifteen Generic Defendants

281. In late 2007 and early 2008, fifteen generic pharmaceutical companies (TEVA Pharmaceuticals USA Inc. (“Teva”); Cobalt Laboratories, Inc. (“Cobalt”); Barr Pharmaceuticals Inc. (“Barr”); Orchid Healthcare (“Orchid”); Lupin Pharmaceuticals, Inc. (“Lupin”); Upsher-Smith Laboratories, Inc. (“Upsher-Smith”); Wockhardt USA Inc. (“Wockhardt”); Genpharm LP (“Genpharm”); Mylan Pharmaceuticals Inc. (“Mylan”); Interpharm Inc (“Amneal”); Ranbaxy Laboratories Limited (“Ranbaxy”); Sun India Pharmaceutical Industries Limited (“Sun”); Dr. Reddy’s Laboratories Inc. (“DRL”); Synthon Laboratories, Inc. (“Synthon”); and Apotex Inc. (“Apotex”) notified Forest of Abbreviated New Drug Applications filed with the FDA, each seeking approval to market a generic version of Namenda® before the expiration of the ‘703 patent.

Public Documents: Ex. 133, *Forest Laboratories Inc. et al v. Lupin Pharmaceuticals Inc. et al.*, Case No. 1:08-cv-00021-LPS, (“‘703 Patent Litigation”) Dkt. No. 1; Ex. 134, *Forest Laboratories, Inc. et al. v. Barr Laboratories, Inc. and Barr Pharmaceuticals Inc.*, Case No. 1:08-cv-00022-LPS, Dkt. No. 1; Ex. 135, *Forest Laboratories, Inc. et al. v. Dr. Reddy’s Laboratories, Inc. et al.*, Case No. 1:08-cv-00052-LPS, Dkt. No. 1; Ex. 136, *Forest Laboratories, Inc. et al. v. Orgenon Pharma, Inc.*, Case No. 1:08-cv-00291-LPS, Dkt. No. 1; Ex. 137, *Forest Laboratories, Inc. et al. v. Apotex Inc. and Apotex Corp.*, Case No. 1:08-cv-336-GMS-LPS, Dkt. No. 1.

Plaintiffs’ Admissions: Am. Compl., ¶¶ 102, 103, 106.

282. Forest responded by filing several patent infringement lawsuits in the District of Delaware in early 2008, asserting infringement of the ‘703 patent under 35 U.S.C. § 271(e)(2)(A).

Public Documents: Ex. 133, ‘703 Patent Litigation, Dkt. No. 1; Ex. 134, *Forest Laboratories, Inc. et al. v. Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc.*, Case

No. 1:08-cv-00022-LPS, Dkt. No. 1; Ex. 135, *Forest Laboratories, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Case No. 1:08-cv-00052-LPS, Dkt. No. 1; Ex. 136, *Forest Laboratories, Inc. et al. v. Orgenus Pharma, Inc.*, Case No. 1:08-cv-00291-LPS, Dkt. No. 1; Ex. 137, *Forest Laboratories, Inc. et al. v. Apotex Inc. and Apotex Corp.*, Case No. 1:08-cv-336-GMS-LPS, Dkt. No. 1

Plaintiffs' Admissions: Am. Compl., ¶¶ 104-105, 108; Ex. 3, Johnston Rep. ¶ 59-60.

283. The court eventually consolidated the cases into a single action and scheduled a claim construction hearing for December 15, 2008 and a trial from April 5 to April 9, 2010.

Public Documents: Exs. 316, 318, 317, 319, '703 Patent Litigation, Dkt. Nos. 76, 83, 114, 117.

Plaintiffs' Admissions: Am. Compl. ¶ 104; DPPs' Statement of Material Facts ISO Count Three, ¶¶ 22, 36, 50, 64, 78, 91, 105; Ex. 3, Johnston Rep. ¶ 61.

284. The consolidated case was before Chief Judge Sleet and Magistrate Judge Stark (now a District Judge).

Public Documents: *See generally* '703 Patent Litigation docket.

## **B. The Namenda Patent Litigation Claim-Construction Ruling**

285. Magistrate Judge Stark conducted a claim construction hearing on December 15, 2008.

Public Documents: Ex. 138, '703 Patent Litigation, Dkt. No. 248.

286. On July 2, 2009, Magistrate Judge Stark issued a Report and Recommendation Regarding Claim Construction, interpreting certain terms of the '703 patent's claims where the parties could not agree on their meaning.

Public Documents: Ex. 139, ‘703 Patent Litigation, Dkt. No. 373

287. In his Report and Recommendation, Magistrate Judge Stark explained that he “largely sided with Plaintiffs” [i.e., Forest] and adopted Forest’s positions on 9 of the 13 disputed issues.

Public Documents: *See generally* Ex. 139, ‘703 Patent Litigation, Dkt. No. 373; *see also id.* at 21 (“Just as I have largely sided with Plaintiffs above, and for the same reasons. I do so here as well.”).

Defendants’ Evidence: Ex. 5, McKelvie Rep. ¶ 56

Plaintiffs’ Admissions: Ex. 140, Direct Purchaser Class Plaintiffs’ Amended Responses to Forest’s Request for Admission No. 12, dated Jul. 19, 2017

288. For the terms where he did not adopt Forest’s proposed constructions verbatim, Magistrate Judge Stark rejected the generics’ proposals and instead crafted his own constructions.

Public Documents: Ex. 139, ‘703 Patent Litigation, Dkt. No. 373 at 17 (For “prevention of cerebral ischemia.” “The Defendants’ proposed constructions, however, are no more persuasive.”), 24 (construing “Alzheimer’s disease” differently than Defendants proposed and construing “Patient diagnosed with Alzheimer’s disease” in accordance with the construction of “Alzheimer’s disease”), 27-28 (disagreeing with Defendants’ construction of “Amount effective to prevent degeneration an loss of nerve cells after ischemia”).

Defendants’ Evidence: Ex. 5, McKelvie Rep. ¶ 56

289. Magistrate Judge Stark rejected the generics’ argument that “cerebral ischemia” (a component of several claim terms) be construed to mean “an acute interruption of blood supply to the brain.”

Public Documents: Ex. 139, ‘703 Patent Litigation, Dkt. No. 373, at 7-17 (construing “cerebral ischemia” and stating on page 9, “I agree that Defendants have properly framed the question presented, but I have concluded that Plaintiffs’ answer is the correct one”).

Defendants' Evidence: Ex. 5, McKelvie Rep. ¶ 58

290. After a review of the patent's specification, the Court explained: "The main points derived from these portions of the specification are that the invention has to do with the central nervous system and not the bloodstream; the problem the invention is directed to addressing is an imbalance of neuronal stimulation mechanisms; and the invention acts on NMDA receptor channels," all of which Magistrate Judge Stark found supported Forest's construction. Thus, Magistrate Judge Stark adopted Forest's proposal and construed the term "cerebral ischemia" to relate to an "imbalance of neuronal stimulation mechanisms."

Public Documents: Ex. 139, '703 Patent Litigation, Dkt. No. 373, at 10-11, 14, 17.

Defendants' Evidence: Ex. 5, McKelvie Rep. ¶ 58

Plaintiffs' Admissions: Ex. 3, Johnston Rep. Ex. K

291. Magistrate Judge Stark construed "prevention of cerebral ischemia" and "treatment of cerebral ischemia" to mean "prevention of an imbalance of neuronal stimulation mechanisms" and "an antagonistic intervention with regard to the . . . (NMDA) receptor channels," respectively. Forest's former chief intellectual property counsel, Charles Ryan, testified "a magistrate judge, who is now a federal district court judge, write a comprehensive Markman opinion, gave us a very strong ruling, and we were prepared to go to trial."

Public Documents: Ex. 139, '703 Patent Litigation, Dkt. No. 373, at 17-20.

Defendants' Evidence: Ex. 367, Charles Ryan Dep. (Nov. 7, 2017) 369:15-370:4.

292. On September 21, 2009, District Judge Sleet issued a decision agreeing with Judge Stark's recommendations on the "cerebral ischemia" issue and nearly every other (save one minor clerical change).

Public Documents: *See generally* Ex. 141, '703 Patent Litigation, Dkt. No. 426.

Defendants' Evidence: Ex. 5, McKelvie Rep. ¶ 57

Plaintiffs' Admissions: Ex. 140, Direct Purchaser Class Plaintiffs' Amended Responses to Forest's Request for Admission No. 13, dated Jul. 19, 2017; Ex. 3, Johnston Rep. ¶ 65-67, Ex. K

### **C. Settlements and Dismissals**

293. When Magistrate Judge Stark issued his Report and Recommendation on July 2, 2009, eleven of the fifteen generic companies Forest had sued remained in the consolidated patent case: (1) Cobalt, (2) Lupin, (3) Teva, (4) Upsher-Smith, (5) Wockhardt, (6) DRL, (7) Genpharm, (8) Interpharm/Amneal, (9) Mylan, (10) Sun, and (11) ApotEx. As for the other four: Orchid's case was transferred to the District of New Jersey in April 2009; Barr and Synthon withdrew their ANDAs in May 2009, causing Forest to dismiss its Complaints against them; and in April 2008, Ranbaxy agreed to a consent judgment that the '703 patent is valid and Ranbaxy's generic product would fall within the claims as construed.

Public Documents: *See generally* Ex. 142, '703 Patent Litigation Docket; *see also* Ex. 142, '703 Patent Litigation Dkt. No. 407 (transferring Orchid to D.N.J.), Ex. 143, Dkt. No. 329 (dismissing Barr); Ex. 144, *Forest Laboratories Inc. et al v. Dr. Reddy's Laboratories, Inc. et al.*, Case No. 1:08-cv-00052-GMS-LPS Dkt. No. 78 (Ranbaxy consent judgment), Ex. 145, *Forest Laboratories, Inc. et al. v. Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc.*, Case No. 1:08-cv-00052-LPS Dkt. No. 87 (dismissing Synthon).

Plaintiffs' Admissions: Ex. 3, Johnston Rep. ¶ 69

294. Nine of the eleven remaining generic defendants (Cobalt, Lupin, Teva, Upsher-Smith, Wockhardt, DRL, Amneal, Sun, and Apotex) reached settlements with Forest by the end of 2009, i.e., within three months of Judge Sleet's September 21, 2009 claim construction decision. The settlements licensed the generics to begin selling generic memantine three months before the expiration of the '703 patent, or three months before the expiration of Forest's pediatric exclusivity period, if Forest were to obtain pediatric exclusivity in the future. Forest dismissed Genpharm from the case on October 9, 2009 after Genpharm withdrew its ANDA in October 2009. DPPs' expert, Prof. Elhauge agreed that the terms of the actual settlement agreements that Forest entered into is consistent with Forest's believing it that it had an extremely high—up to 94.9%—likelihood of success in the patent suit.

Public Documents: '703 Patent Litigation Dkt. Nos. 409 (Ex. 147), 412 (Ex. 148), 413 (Ex. 149), 415 (Ex. 150), 416 (Ex. 320), 417 (Ex. 151), 418 (Ex. 152), 419 (Ex. 153), 432 (Ex. 154), 434 (Ex. 155), 437 (Ex. 156), 439 (Ex. 157), 450 (Ex. 158), 452 (Ex. 159), 453 (Ex. 160), 458 (Ex. 161), 464 (Ex. 162).

Defendants' Evidence: Ex. 5, McKelvie Rep. ¶ 60; Ex. 340, Eric Agovino Dep. (Sept. 12, 2017) 86:22-87:7 ("I can't remember exactly when, but the settlement started to pick up pace after the Markman decision in this case."); Ex. 339, Charles Ryan Dep. (Sept. 7, 2017) 186:4-9 (Q. Do you recall when the first settlement inquiries were made in connection with the patent litigations? A. It was shortly after we had a successful Markman hearing."); Ex. 324, David Solomon Dep. (Sept. 7, 2017) 279:20-281:16; Ex. 29, Settlement Agreement between Forest, Merz, and Dr. Reddy's (FRX-AT-00000001-037); Ex. 27, Settlement Agreement between Forest, Merz, and Cobalt (FRX-AT-00000038-061); Ex. 26, Settlement Agreement between Forest, Merz, and Sun (FRX-AT-00000112-147); Ex. 24, Settlement Agreement between Forest, Merz, and Upsher-Smith (FRX-AT-00000148-183); Ex. 28, Settlement Agreement between Forest, Merz, and Teva (FRX-AT-00000184-217); Ex. 22, Settlement Agreement between Forest, Merz, and Amneal (FRX-AT-00000218-252); Ex. 23, Settlement Agreement between Forest, Merz, and Apotex (FRX-AT-00000274-298); Ex. 32, Settlement Agreement between Forest, Merz, Orogenus, and Orchid (FRX-AT-00000380-402); Ex. 25, Settlement Agreement between Forest, Merz, and Wockhardt (FRX-AT-00000076).

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count Three, ¶¶ 23, 37, 51, 65, 79, 92, 106; Ex. 3, Johnston Rep. ¶ 69; Ex. 122, Elhauge Rep. II ¶ 67.

295. Within two months of Judge Sleet's opinion, just two generics remained in the consolidated case in the District of Delaware: Mylan and Lupin. Lupin settled by the end of the year, leaving only Mylan. Orchid, which had been transferred to the District of New Jersey, settled in April 2010.

Public Documents: Ex. 163, '703 Patent Litigation, Dkt. No. 466; Ex. 146, *Forest Laboratories, Inc., et al. v. Orgenus Pharma Inc., et al.*, Case No. 3:09-cv-05105-MLC-DEA (D. N. J.), Dkt. No. 26.

Defendants' Evidence: Ex. 5, McKelvie Rep. ¶ 61; Ex. 31, Settlement Agreement between Forest, Merz, and Lupin (FRX-AT-00000340-362)

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count Three, ¶ 51; Ex. 3, Johnston Rep. ¶ 69

296. The timing of the non-Mylan settlements is as follows:

Date	Event
<i>July 2, 2009</i>	<i>Judge Stark's Claim Construction Decision</i>
September 2, 2009	Amneal settlement
September 8, 2009	Upsher-Smith settlement
September 9, 2009	Apotex settlement
September 10, 2009	Wockhardt settlement
<i>September 21, 2009</i>	<i>Judge Sleet's Claim Construction Decision</i>
October 8, 2009	Genpharm dismissed (ANDA withdrawn)
October 9, 2009	Sun settlement
October 19, 2009	Cobalt settlement
November 5, 2009	Teva settlement
December 14, 2009	DRL settlement

Date	Event
February 11, 2010	Lupin settlement
April 26, 2010	Orchid settlement (after transfer to D.N.J. in March 2009)

Public Documents: ‘703 Patent Litigation Dkt. Nos. 409 (Ex. 147), 412 (Ex. 148), 413 (Ex. 149), 415 (Ex. 150), 416 (Ex. 320), 417 (Ex. 151), 418 (Ex. 152), 419 (Ex. 153), 432 (Ex. 154), 434 (Ex. 155), 437 (Ex. 156), 439 (Ex. 157), 450 (Ex. 158), 452 (Ex. 159), 453 (Ex. 160), 458 (Ex. 161), 464 (Ex. 162).

Defendants’ Evidence: Ex. 29, Settlement Agreement between Forest, Merz, and Dr. Reddy’s (FRX-AT-00000001-037); Ex. 27, Settlement Agreement between Forest, Merz, and Cobalt (FRX-AT-00000038-061); Ex. 26, Settlement Agreement between Forest, Merz, and Sun (FRX-AT-00000112-147); Ex. 24, Settlement Agreement between Forest, Merz, and Upsher-Smith (FRX-AT-00000148-183); Ex. 28, Settlement Agreement between Forest, Merz, and Teva (FRX-AT-00000184-217); Ex. 22, Settlement Agreement between Forest, Merz, and Amneal (FRX-AT-00000218-252); Ex. 23, Settlement Agreement between Forest, Merz, and Apotex (FRX-AT-00000274-298); Ex. 31, Settlement Agreement between Forest, Merz, and Lupin (FRX-AT-00000340-362); Ex. 32, Settlement Agreement between Forest, Merz, Orgenus, and Orchid (FRX-AT-00000380-402); Ex. 25, Settlement Agreement between Forest, Merz, and Wockhardt (FRX-AT-00000076).

Plaintiffs’ Admissions: DPPs’ Statement of Material Facts ISO Count Three, ¶¶ 23, 37, 51, 65, 79, 92, 106; Ex. 3, Johnston Rep. ¶ 69.

#### **D. The Mylan Litigation**

297. Forest and Merz and Mylan filed a joint pretrial order on February 26, 2010, which included witness lists and proposed findings of fact and conclusions of law from both Forest and Mylan.

Defendants’ Evidence: Ex. 166, Pretrial Order.

Plaintiffs’ Admissions: Ex. 3, Johnston Rep. ¶ 70

##### **i. Infringement**

298. Forest and Merz argued that the use of Mylan's generic memantine product by physicians or patients would infringe the asserted claims of the '703 patent and that Mylan also induced or contributed to that infringement.

Public Documents: Ex. 135, *Forest Laboratories Inc. v. Dr. Reddy's Laboratories Inc. et al.*, Case No. 1:08-cv-00052-LPS, Dkt. No. 1; Ex. 167, *Forest Laboratories Inc. v. Dr. Reddy's Laboratories Inc. et al.*, Case No. 1:08-cv-00052-LPS, Dkt. No. 31..

Defendants' Evidence: Ex. 166, Pretrial Order, Exhibit 12, ¶ 35.

299. Forest and Merz planned to call expert witnesses Dr. Rachelle Doody and Dr. Roberto Malinow to address infringement.

Defendants' Evidence: Ex. 166, Pretrial Order, Exhibit 7 and Exhibit 9 (Dr. Doody was expected to testify as to whether users of Mylan's generic product would "infringe any of the asserted claims of the '703 patent" and "whether Mylan [would] induce or contribute to such infringement[.]" Dr. Malinow was expected to address "memantine's mechanism of action, its neurobiological characteristics, and preclinical aspects of Alzheimer's disease[.]")

300. Mylan offered Dr. John Olney to address infringement.

Defendants' Evidence: Ex. 166, Pretrial Order, Exhibit 8 and Exhibit 10 ("Dr. Olney [was] expected to testify that Mylan's proposed memantine hydrochloride ANDA product (and methods for its administration) [would] not infringe the asserted claims of the '703 patent. . . .").

301. Dr. Olney opined that the dosages of memantine indicated in Mylan's package insert would not "approach levels necessary to prevent an imbalance of neuronal stimulation mechanisms" or act as an NMDA receptor antagonist. However, Dr. Olney admitted in his deposition that memantine does antagonize NMDA receptors, and that the majority of the scientific community does not question memantine's mechanism of action in humans.

Defendants' Evidence: Ex. 168, Rebuttal Expert Report of John Olney, M.D., MNAT\_0001112-1157 ("Olney Rep.") ¶ 66.

Undisputed Record Evidence: Ex. 342, Deposition Testimony of John Olney ("Olney Dep.") (Jan. 29, 2010) (MYLMEMA\_005665-739) 63:15-20, 112:16-114:12 (testifying that the scientific community does not question that memantine is an NMDA antagonist at an effective dose).

302. The scientific community agrees that memantine works through NMDA receptor antagonism. Forest's experts Dr. Malinow, Dr. Farlow, and Dr. Doody all would have testified that NMDA receptor antagonism is memantine's accepted mechanism of action.

Defendants' Evidence: *See generally* Ex. 169, Supplemental Expert Report of Roberto Malinow, M.D., Ph.D., MNAT\_0000937-945 ("Malinow Supp. Rep."); Ex. 170, Opposition Expert Report of Martin R. Farlow, M.D., MNAT\_0000524-656 ("Farlow Rep.") ¶ 158; Ex. 171, Expert Report of Dr. Rachelle S. Doody Regarding Mylan, MNAT\_0000411-523 ("Doody Rep.") ¶ 93.

Plaintiffs' Admissions: Ex. 343, Deposition of Nathan Herrmann ("Herrmann Dep.") (Nov. 2, 2017) 59:19-60:6, 60:15-20 (testifying that the vast majority of the scientific community accepts the proposition that memantine's mechanism of action in Alzheimer's patients is NMDA receptor antagonism); Ex. 344, Deposition of Lon S. Schneider, M.D. ("Schneider Dep.") (Oct. 27, 2017) 50:15-22, 53:14-18 ("... Do you have any reason to disagree that Memantine's action is an NMDA antagonist?... " "... I have no reason to disagree with it.")

Undisputed Record Evidence: Ex. 345, Deposition Testimony of Jerry Joseph Buccafusco ("Buccafusco Dep.") (Jan. 19, 2010) (MYLMEMA\_005595-664) 28:18-29:11 (testifying that the proposed mechanism of action of the compound in the '703 patent is "the ability of adamantane derivatives particularly memantine to interact with the NMDA subtype of glutamate receptor and inhibit its function" which he believed is "one of the mechanisms of action" for memantine.); Ex. 346, Deposition Testimony of Paul Spencer Fishman ("Fishman Dep.") (Jan. 20, 2010) (MYLMEMA\_005089-155) 89:12-17 ("It is said in the product label" that Namenda operates through an NMDA receptor channel antagonism."); Ex. 342, Olney Dep. 63:15-20, 112:16-113:25, 114:1-12 (testifying that the scientific community does not question that memantine is an NMDA antagonist at an effective dose).

303. Mylan admitted in an interrogatory response that memantine, the active ingredient in Mylan's product, worked through NMDA receptor antagonism: "the mechanism of action by which memantine works is that of an NMDA receptor antagonism. . . ."

Defendants' Evidence: Ex. 172, Mylan's Supplemental Response to Plaintiffs' Interrogatory No. 2, FRX-AT-04228504-556 at FRX-AT-04228539; Ex. 166, Pretrial Order, Exhibit 11, ¶ 80.

304. Mylan's proposed prescribing information and other ANDA submissions to the FDA recognized that memantine works as an NMDA receptor antagonist.

Defendants' Evidence: Ex. 171, Doody Rep. ¶ 22-24.

Undisputed Record Evidence: Ex. 173, MYLMEMA\_000343 ("Memantine hydrochloride is an orally active N-methyl-D-aspartate (NMDA) receptor antagonist which is used for the treatment of moderate to severe dementia of the Alzheimer's type."); Ex. 174, MYLMEMA\_000855; Ex. 175, MYLMEMA\_000959; Ex. 176, MYLMEMA\_001181, 1207 ("Memantine hydrochloride is an orally active NMDA receptor antagonist") ("Memantine hydrochloride is a low to moderate affinity uncompetitive NMDA antagonist"); Ex. 177, MYLMEMA\_001824 ("Memantine is a low-moderate affinity, uncompetitive N-methyl-D-aspartate (NMDA) receptor antagonist with strong voltage dependency. . .").

## **ii. Anticipation**

305. Mylan identified five references for its anticipation argument: (1) Ambrozi; (2) Marcea; (3) Tempel; (4) Schäfer and Thiery, *Memantine improves the cerebral performance in the elderly*, Psycho. 12:8-18 (1984); and (5) Fünfgeld (1988). The PTO considered at least Ambrozi, Marcea, Tempel, and Fünfgeld.

Public Documents: Ex. 7, '703 Reexam File History, e.g. p. 5, 28, 46, 62, 115, 176, and 177.

Defendants' Evidence: Ex. 166, Pretrial Order, Exhibit 12, ¶ 133; Ex. 178, Fishman Rep. ¶¶ 27-50.

Plaintiffs' Admissions: Ex. 3, Johnston Rep. ¶¶ 128, 130; Ex. 344, Deposition Testimony of Lon Schneider ("Schneider Dep") (Oct. 27, 2017) 30:4-15.

306. None of the references *expressly* disclosed a treatment of patients diagnosed with Alzheimer’s disease, as characterized by the Diagnostic and Statistical Manual of Mental Disorders, version III-R.

Defendants’ Evidence: Ex. 347, Deposition Testimony of David A. Greenberg, M.D., Ph.D. (Feb. 18, 2010) (“Greenberg Dep.”) (FRX-AT-04578462-FRX-AT-04578493) 39:1-17 (testifying that “organic brain syndrome” is a very nonspecific term and not dispositive as to whether or not an individual has Alzheimer’s disease); Ex. 170, Farlow Rep. ¶¶ 68, 72-77, 81; Ex. 166, Pretrial Order, Exhibit 11, ¶¶ 115-26.

Plaintiffs’ Admissions: Ex. 344, Schneider Dep. 135:11-136:10 (“[D]oes the paper [Ambrozi] say this – at least one person or does the paper say these participants have been diagnosed with Alzheimer’s disease? That quote – flat line doesn’t exist.”), 156:15-157:1 (“I agree with you that it [Schafer] does not say the word ‘Alzheimer’s disease.’ It does not say these patients had Alzheimer’s disease.”), 169:24-170:10 (“Similarly, there is – there is no individual patient there [Marcea and Tempel] identified as – having Alzheimer’s disease.”)

Undisputed Record Evidence: Ex. 346, Fishman Dep. 77:2-11, 78:9-23.

307. Mylan’s anticipation expert, Dr. Fishman did not mention NMDA receptors in his report. He testified in his deposition that he “did not consider” whether patients receiving memantine in the prior art on which he relied experienced NMDA receptor antagonism, and that he saw “no direct evidence in those articles whether or not patients are being treated for an imbalance of neuronal—I didn’t see any evidence for that claim.”

Plaintiffs’ Admissions: *See generally* Ex. 178, Expert Report of Paul Spencer Fishman, MNAT\_0000657-722 (“Fishman Rep.”)

Undisputed Record Evidence: Ex. 346, Fishman Dep. 76:22-78:23.

### **iii. Obviousness**

308. Mylan’s obviousness theory was based on the same articles it identified in its anticipation argument.

Defendants' Evidence: Ex. 166, Pretrial Order, Exhibit 12, ¶¶ 133-34, 159; Ex. 178, Fishman Rep. ¶ 57.

309. Mylan's expert Dr. Fishman opined that one of ordinary skill in the art would have known to administer memantine to patients with Alzheimer's disease because the patients treated with memantine in Mylan's identified studies likely included individuals with Alzheimer's disease.

Defendants' Evidence: Ex. 178, Fishman Rep. ¶¶ 57-58

310. Separately, Mylan's expert Dr. Buccafusco opined that it would have been obvious to administer memantine to patients with Alzheimer's disease based on the fact that a different molecule, amantadine, had previously been administered to patients with Alzheimer's disease prior to 1989.

Defendants' Evidence: *See generally* Ex. 179, Expert Report of Jerry Joseph Buccafusco, MNAT\_0000333-388 ("Buccafusco Rep.")

311. No prior art to the '703 patent makes any express statement regarding memantine's ability to antagonize NMDA receptors. Neither Dr. Buccafusco nor Dr. Fishman offered any opinion in their report as to why memantine's NMDA receptor antagonism would have been obvious.

Defendants' Evidence: Ex. 347, Greenberg Dep. 93:20-94:5; Ex. 166, Pretrial Order, Exhibit 11, ¶ 129; Ex. 170, Farlow Rep. ¶¶ 53-60; *see also* Ex. 178, Fishman Rep. and Ex. 179, Buccafusco Rep.

312. Prior to 1989, memantine was believed to be a dopamine agonist. Dr. Buccafusco testified that "it would be—would have been surprising [to person of skill in the art that

memantine acted through an NMDA mechanism of action]. It was surprising to me when I first heard about it.

Defendants' Evidence: Ex. 345, Buccafusco Dep. 30:14-31:4.

313. Plaintiffs' purported expert witness George Johnston admitted, "Mylan did not present a strong rebuttal to Forest and Merz's arguments on secondary considerations" of nonobviousness.

Plaintiffs' Admissions: Ex. 3, Johnston Rep. ¶ 185.

#### **iv. Enablement**

314. Mylan and its experts Dr. Buccafusco and Dr. Greenberg contended that a person of ordinary skill in the art would not have been convinced that an NMDA receptor antagonist would be beneficial for Alzheimer's disease. Mylan argued that "[e]nablement is also closely related to the utility requirement under 35 U.S.C. § 101, 'prevent[ing] mere ideas from being patented.'" According to Mylan, "enablement requires that the patent's written description disclose a credible and practical utility of the invention at the time of filing of the application." Mylan claimed that the '703 patent did not do so because its data suggested to persons of skill in the art that memantine would *not* treat Alzheimer's disease and might actually be harmful for Alzheimer's patients.

Defendants' Evidence: Ex. 166, Pretrial Order, Exhibit 12, ¶ 179-180; Ex. 179, Buccafusco Rep. ¶¶ 22-25; Ex. 180, Expert Report by David A. Greenberg, MNAT\_0001158-184 ("Greenberg Rep.") ¶¶ 12-17.

315. Forest's expert, Dr. Malinow opined that the information disclosed in the '703 patent was sufficient for a person of ordinary skill to understand how to administer memantine to

a patient suffering from Alzheimer’s disease. The ‘703 patent states: “It has been found unexpectedly that the use of these compounds [including memantine] prevents an impairment or further impairment, i.e., degeneration and loss of nerve cells, after ischemia. Therefore, the [compounds disclosed in the ‘703 patent] . . . are especially suited for the prevention and treatment of cerebral ischemia after . . . Alzheimer’s disease.”

Public Documents: Ex. 2, ‘703 patent, col.3 ll.7-16.

Defendants’ Evidence: Ex. 181, Malinow Opp. Rep. ¶¶ 52, 54-73.

316. Mylan’s expert Dr. Buccafusco’s testimony was inconsistent and contradictory in that he testified both that a person of skill would have expected memantine to treat Alzheimer’s disease, and that a person of ordinary skill would not have a reasonable expectation in carrying out the methods of the claimed invention, i.e., using memantine to treat Alzheimer’s disease. For example, he testified both that a person of skill in the relevant art in 1989 would “not have been surprised that memantine could be used to treat Alzheimer’s,” and that “that same person” would not have had “a reasonable expectation of success in practicing the claimed invention.”

Undisputed Record Evidence: Ex. 345, Buccafusco Dep. 42:1-11, 42:1-48:4.

317. Mylan’s expert Dr. Fishman testified that as of 1989, a person of skill who was aware of what was well-known in the art and had read the ‘703 patent’s specification “would have been able to apply the invention.”

Undisputed Record Evidence: Ex. 346, Fishman Dep. 81:15-83:1.

**E. No Evidence of Any Generics Planning an “At-Risk” Launch**

318. Plaintiffs’ expert Prof. Einer Elhauge assumes that no at-risk entry would occur during litigation “given the low generic profits” and “the large potential damages” from at-risk entry.

Plaintiffs’ Admissions: Ex. 121, Elhauge Rep. I at 19; Ex. 335, Elhauge (Sep. 29) Dep. 87:7-9.

319. Generics would not have expected Mylan to enter at risk.

Plaintiffs’ Admissions: Ex. 121, Elhauge Rep. I ¶ 19.

320. Dr. Reddy’s did not consider launching generic memantine at risk.

Undisputed Record Evidence: Ex. 328, McCormick Dep. (Dr. Reddy’s) 123:10-14.

321. Amneal had no plans of launching generic memantine earlier than January 2015.

Undisputed Record Evidence: Ex. 327, K. Gupta (Amneal) Dep. 91:5-8.

322. Sun did not consider launching generic memantine at risk and testified that an at risk launch occurs in very rare circumstances.

Undisputed Record Evidence: Ex. 330, Nadkarni (Sun) Dep. 128:18-129:6.

323. As of October 2015 Teva decided to shut down its launch of generic memantine due to analytical issues.

Undisputed Record Evidence: Ex. 350, Cavanaugh (Teva) Dep. 72:25-73:11.

324. Wockhardt has an internal policy of never launching a product at risk unless approved by the legal department.

Undisputed Record Evidence: Ex. 351, Venkatesan (Wockhardt) Dep. 209:9-15, 210:19-211:11.

325. Torrent's witness testified that was preferable to have a license agreement in place to launch its generic memantine product.

Undisputed Record Evidence: Ex. 352, S. Gupta (Torrent) Dep. 138:22-139:21.

326. Torrent has only launched one product at risk, out of its approximately 60 products. Torrent has not launched more at risk based on legal advice.

Undisputed Record Evidence: Ex. 352, S. Gupta (Torrent) Dep. 59:2-15.

327. Lupin did not consider launching generic memantine at risk.

Undisputed Record Evidence: Ex. 188, Lupin's Motion to Quash Hr. Tr. 37:4-18.

**F. No Evidence that Forest Considered Launching a Namenda IR Authorized Generic in the 2010-2012 Timeframe**

328. Forest did not consider launching a Namenda IR Authorized Generic because there were multiple first filers and the value for Forest would not be significant.

Defendants' Evidence: Ex. 353, Solomon (NYAG) Dep. 83:7-9, 85:23-87:3 (When "there is a single generic entrant, then the value of an authorized generic is much greater because you have a six-month period where there may only be one generic product and so you as a branded company might say, well, we can share that generic market and so we're going to create an authorized generic. In this case Venkatesanwo, this was a five-year Waxman-Hatch [sic] product, there was a date certain, there were multiple filers, the day this product goes generic there will be many generic versions of Namenda IR, so the value for us of an authorized generic was not significant. Now, now that the company is party of Actavis, they might take a different view, I don't know, but certainly for Forest,

we never viewed an authorized generic of Namenda IR as being something of – we had a few generic products, but we were not able to effectively compete in these big generic markets against people like Teva, Mylan, Actavis, and so on, so we wouldn't have considered that as something that made sense for us.”); Ex. 354, Saunders (NYAG) Dep. 354:9-356:19 (“[A]s of today I am not allowing them to do an authorized generic . . . I want our people focused on XR and we certainly don't have the fixed dose combination out yet so we've got a lot of work to do there, it is only one part of the equation.”); Ex. 324, Solomon (Sep. 7) Dep. 58:7-60:15; Ex. 325, Snyder Dep. 80:6-23 (“there was never any discussion about launching [a Namenda IR] authorized generic at Forest”), 95:4-17.

329. Actavis was in the generics business and found that there would be interest in launching generic memantine in 2015.

Defendants' Evidence: Ex. 325, Snyder Dep. 97:22-98:14.

330. “[W]hat Actavis did would not necessarily have been the same thing that Forest would have done had Actavis not acquired Forest.”

Defendants' Evidence: Ex. 325, Snyder Dep. 76:14-22.

#### **G. No Evidence an Earlier Entry Date Was Considered for Settlements**

331. Forest was unwilling to negotiate with the Generic Defendants a launch date earlier than three months prior to the '703 patent expiration.

Defendants' Evidence: Ex. 340, Agovino Dep. 75:6-76:20; Ex. 339, Ryan (Sep. 7) Dep. 199:9-200:15.

Undisputed Record Evidence: Ex. 329, Silber (Mylan) Dep. 24:8-25:20; Ex. 34, KE00000169; Ex. 190, KE00000302.

Plaintiffs' Admissions: Ex. 335, Elhauge (Sep. 29) Dep. 56:19-57:1 (conceding that no witness involved in real life negotiations between Forest and Mylan has testified that a 2012 settlement was clearly feasible).

#### H. There is No Evidence that Generics Could Have Entered in 2012

332. There is no evidence that Mylan could have negotiated with Forest for a 2012 settlement date in the real world.

Defendants' Evidence: Ex. 339, Ryan (Sep. 7) Dep. 199:9-200:15 (Forest was not willing to negotiate with Mylan for a 2012 launch date), Ex. 367, Ryan (Nov. 7) Dep. 394:21-395:2; Ex. 340, Agovino Dep. 75:6-76:20 (Forest was unwilling to negotiate with Mylan a launch date earlier than three months prior to the '703 patent expiration); Ex. 366, Solomon (Nov. 15) Dep. 421:12-422:6 ("We wouldn't have considered that at all.").

Undisputed Record Evidence: Ex. 329, Silber (Mylan) Dep. 24:8-25:20; Ex. 34, KE00000169; Ex. 190, KE00000302

Plaintiffs' Admissions: Ex. 335, Elhauge (Sep. 29) Dep. 56:19-57:1 (conceding that no witness involved in real life negotiations between Forest and Mylan has testified that a 2012 settlement was clearly feasible).

333. At the depositions of generic manufacturers, Plaintiffs' did not ask any questions regarding the generics' ability to manufacture and launch generic Namenda in 2012.

Undisputed Record Evidence: Ex. 355, Curia (Mylan) Dep. 112:19-119:24 (asking Ms. Curia about manufacturing capabilities in 2013-2015); Ex. 328, McCormick (DRL) Dep. 137:6-138:4 (asking whether there were any problems with other products DRL manufactured in 2013, or whether there were supply issues starting in 2013), 204:9-24 (asking whether DRL could have launched in 2013), 215:24-5 (asking questions based on witness' time at DRL, witness started working at DRL in 2013), 228:23-229:7 (asking about 2013-2015), (no reference to 2012 in entire deposition); Ex. 327, Gupta (Amneal) Dep. 12:4-7 (only reference to 2012 in the Amneal deposition refers to witness' start date at company), 165:7-167:5 (asking whether anything would have prevented Amneal from requesting final approval in 2013), 201:24-203:12 (asking whether anything would prevent Amneal from manufacturing and launching in 2013 or 2014); Ex. 352, Gupta (Torrent) Dep. 60:6-8 (the only mention of 2012 in Torrent deposition refers to witness' start date at company); Ex. 330, Nadkarni (Sun) Dep. 216:21-217:2 (asks merely whether Sun would take same preparatory steps in 2012 that it did for 2015 launch and whether Sun would have wanted to be on the market as early as possible in 2012); Ex. 350, Cavanaugh (Teva) Dep. (witness was not asked about ability to launch in 2012); Ex. 331, Rabinovic (Teva) Dep. (no mention of 2012 in entire deposition); Ex. 351, Venkatesan (Wockhardt) Dep. (no mention of 2012 in entire deposition); Ex. 334, Wilk (Orgenon) 58:17-59:2 (first two mentions of 2012 are about a change to the settlement agreement), 146:23-147:2 (third mention of 2012 is about date of final approval).

334. Plaintiffs' expert, Janet DeLeon admitted that there are no documents that demonstrate the generics' ability to launch in 2012 and explained that she did not examine any documents or evidence demonstrating the generics' supply capabilities, manufacturing equipment, or capacity as of 2012.

Plaintiffs' Admissions. Ex. 356, DeLeon Dep. 90:17-91:11, 133:2-15, 143:24-144:8.

335. Many generic companies had issues during launch planning or expressed doubts about the business justifications for launching, such that it is not certain they would have launched in 2012.

Undisputed Record Evidence: Ex. 355, Curia (Mylan) Dep. 112:19-113:23 (Mylan had fewer manufacturing facilities worldwide in 2013 than it does now); Ex. 328, McCormick (DRL) Dep. 18:8-19:23 (DRL expressed that the more competition targeting the same product, the less attractive an opportunity becomes); Ex. 191, Sun Exhibit 10; Ex. 330, (Sun) Dep. 71:11-73:7 (showing that manufacturing, supply, and other issues have prevented Sun from hitting launch date targets in the past); Ex. 350, Cavanaugh (Teva) Dep. 69:16-73:11 (in 2015 Teva was dissuaded to continue working on resolving USP method issues because there was too much competition in the market); Ex. 192, LPI-NMDA-00004892 at 4895 (showing that in 2013 Lupin's API manufacturing was on hold due to issues with raw material quality).

336. Several generic companies had issues launching on time in 2015, demonstrating that many issues can prevent a timely launch.

Undisputed Record Evidence: Ex. 352, Gupta (Torrent) Dep. 30:9-31:10 (Torrent did not begin selling generic Namenda IR until December 2015, two months after it received final approval from the FDA); Ex. 350, Cavanaugh (Teva) Dep. 58:22-60:23 (Teva was unable to launch in 2015 due to USP method issues that it was unable to resolve before its scheduled launch date); Ex. 351, Venkatesan (Wockhardt) Dep. 47:18-51:5 (Wockhardt was unable to obtain final approval from the FDA until September 4, 2015, and could not launch generic Namenda IR until November 2015, four months after it could have entered with FDA approval under Wockhardt's settlement agreement with Forest).

#### **IV. GENERIC SETTLEMENTS: NO CONSPIRACY**

##### **A. The Namenda IR Patent Settlements Contained Generic Entry Early Acceleration Clauses**

337. Each of the Generic Manufacturer's settlement agreements contained a provision that permitted the Generic Manufacturer's entry date to automatically accelerate under certain conditions.

Defendants' Evidence: Ex. 29, FRX-AT-00000001 at 0023-0024 §§ 4.3-4.5; Ex. 27, FRX-AT-00000038 at 0061 §§ 4.3-4.5; Ex. 25, FRX-AT-00000076 at 0098 §§ 4.3-4.5; Ex. 26, FRX-AT-00000112 at 0134 §§ 4.3-4.5; Ex. 24, FRX-AT-00000148 at 0169-0170 §§ 4.3-4.5; Ex. 28, FRX-AT-00000184 at 0207 §§ 4.3-4.5; Ex. 22, FRX-AT-00000218 at 0239-0240 §§ 4.3-4.5; Ex. 31, FRX-AT-00000340 at 0364 §§ 4.3-4.5; Ex. 32, FRX-AT-00000380 at 0403 §§ 4.3-4.5; Ex. 33, FRX-AT-00000428 at 0450-0451 §§ 4.3-4.5.

Plaintiffs' Admissions: DPPs' Opp'n to Mot. to Dismiss at 3, 12.

338. In the event Forest granted another generic manufacturer an earlier entry date via a settlement and license agreement, the Generic Entry Early Acceleration Clause provided for the settling Generic Manufacturer's entry date to automatically accelerate to match the earlier entry date.

Defendants' Evidence: Ex. 29, FRX-AT-00000001 at 0023-0024 § 4.3; Ex. 27, FRX-AT-00000038 at 0061 § 4.3; Ex. 25, FRX-AT-00000076 at 0098 § 4.3; Ex. 26, FRX-AT-00000112 at 0134 § 4.3; Ex. 24, FRX-AT-00000148 at 0169-0170 § 4.3; Ex. 28, FRX-AT-00000184 at 0207 § 4.3; Ex. 22, FRX-AT-00000218 at 0239-0240 § 4.3; Ex. 31, FRX-AT-00000340 at 0364 § 4.3; Ex. 32, FRX-AT-00000380 at 0403 § 4.3; Ex. 33, FRX-AT-00000428 at 0450-0451 § 4.3.

339. In the event a third party obtained a final court decision that the '703 patent was invalid, unenforceable, or non-infringed, the Generic Entry Early Acceleration Clause provided for each of the settling Generic Manufacturer's entry date to automatically accelerate to match the earlier entry date.

Defendants' Evidence: Ex. 29, FRX-AT-00000001 at 0024 § 4.4; Ex. 27, FRX-AT-00000038 at 0061 § 4.4; Ex. 25, FRX-AT-00000076 at 0098 § 4.4; Ex. 26, FRX-AT-00000112 at 0134 § 4.4; Ex. 24, FRX-AT-00000148 at 0170 § 4.4; Ex. 28, FRX-AT-00000184 at 0207 § 4.4; Ex. 22, FRX-AT-00000218 at 0240 § 4.4; Ex. 31, FRX-AT-00000340 at 0364-0365 § 4.4; Ex. 32, FRX-AT-00000380 at 0404 § 4.4; Ex. 33, FRX-AT-00000428 at 0451 § 4.4.

340. In the event a third party launched a product “at-risk”—that is, during the patent period and prior to a court finding of invalidity, unenforceability, or non-infringement—the Generic Entry Early Acceleration Clause allowed each settling Generic Manufacturer to accelerate its entry date and enter at-risk.

Defendants' Evidence: Ex. 29, FRX-AT-00000001 at 0024 § 4.5; Ex. 27, FRX-AT-00000038 at 0061-0062; Ex. 25, FRX-AT-00000076 at 0098-0099; Ex. 26, FRX-AT-00000112 at 0134-0135; Ex. 24, FRX-AT-00000148 at 0170-0171; Ex. 28, FRX-AT-00000184 at 0207-0208; Ex. 22, FRX-AT-00000218 at 0240-0241; Ex. 31, FRX-AT-00000340 at 0365-0366; Ex. 32, FRX-AT-00000380 at 0404; Ex. 33, FRX-AT-00000428 at 0451-0452.

**B. Generic Entry Early Acceleration Clauses Provided the Same Protection that Generics Manufacturer Were Entitled to Under Hatch-Waxman**

341. Under the Hatch-Waxman statutory scheme, each first filing Generic Manufacturer, with an approved ANDA share the 180-day exclusivity period and may enter the market concurrently with the other first filing generic manufacturers.

Plaintiffs' Admissions: Ex. 193, Amended Expert Report of Dr. Russell L. Lamb (“Lamb Rep. I”) ¶ 20.

Public Sources: Maryll Toufanian, J.D., Capt. Martin Shumer, R.Ph., *Hatch-Waxman 101*, FDA, <https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM445610.pdf>

342. The Generic Entry Early Acceleration Clause included in each settlement agreement provided each first filing Generic Manufacturers with the same rights to enter the market that each Generic Manufacturer had under the Hatch-Waxman statutory scheme.

Undisputed Record Evidence: Ex. 352, Gupta (Torrent) Dep. 53:16-54:5, 56:8-15.

Defendants' Evidence: Ex. 29, FRX-AT-00000001 at 0023-0024 §§ 4.3-4.5; Ex. 27, FRX-AT-00000038 at 0061 §§ 4.3-4.5; Ex. 25, FRX-AT-00000076 at 0098 §§ 4.3-4.5; Ex. 26, FRX-AT-00000112 at 0134 §§ 4.3-4.5; Ex. 24, FRX-AT-00000148 at 0169-0170 §§ 4.3-4.5; Ex. 28, FRX-AT-00000184 at 0207 §§ 4.3-4.5; Ex. 22, FRX-AT-00000218 at 0239-0240 §§ 4.3-4.5; Ex. 31, FRX-AT-00000340 at 0364 §§ 4.3-4.5; Ex. 32, FRX-AT-00000380 at 0403 §§ 4.3-4.5; Ex. 33, FRX-AT-00000428 at 0450-0451 §§ 4.3-4.5; Ex. 54, Fowdur Rep. ¶¶ 78-79, 83.

Plaintiffs' Admissions: Ex. 193, Lamb Rep. I ¶ 20.

Public Sources: Maryll Toufanian, J.D., Capt. Martin Shumer, R.Ph., *Hatch-Waxman 101*, FDA, <https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM445610.pdf>

### **C. No Evidence of a Conspiracy with or Between Generic Defendants**

343. Plaintiffs have identified no evidence that the settlement agreements were a product of an agreement between and among each Generic Manufacturer.

Plaintiffs have not identified any such evidence.

344. Plaintiffs have identified no evidence that any Generic Manufacturer communicated with one another during their negotiations of the Namenda Patent Settlements Agreements.

Plaintiffs have not identified any such evidence.

345. Each Generic Manufacturer who testified in this case stated they did not speak with other Generic Manufacturers about their negotiations with Forest during the Patent Litigation, and there is no contrary evidence.

Undisputed Record Evidence: Ex. 328, McCormick (DRL) Dep. 152:20-153:8 (“I was not aware of any discussions that happened between Dr. Reddy’s and others, ANDA filers.”); Ex. 329, Silber (Mylan) Dep. 93:3-8; Ex. 331, Rabinovic (Teva) Dep. 44:18-45:5 (“Q. At no time during those settlement negotiations did Teva communicate with any other generic defendants in that case regarding the terms of the Namenda settlement agreement that they were entering into with Forest. Correct? . . . A. That is correct.”); Ex. 352, Gupta (Torrent) Dep. 60:12-15 (“Torrent didn’t discuss the terms of this settlement agreement with other generic manufacturers, did it? A. No, it did not.”); Ex. 351, Venkatesan (Wockhardt) Dep. 159:2-160:4 (A. “It is my understanding in speaking with our former general counsel that we had no knowledge what other defendants are [*sic*] doing [in their settlement negotiations with Forest].”); Ex. 334, Wilk (Orgenus) Dep. 210:8-12; Ex. 327, Gupta (Amneal) Dep. 119:8-119:9 (Q. “At no time during those negotiations did Amneal communicate with any of the other generic defendants regarding the terms of any Namenda settlement agreements that they were negotiating, correct? A. Yes.”); Ex. 330, Nadkarni (Sun) Dep. 129:18-131:3 (“Q. Before Sun settle the patent litigation, did it discuss the terms of the patent litigation settlements with any other generic memantine manufacturers? A. No.”).

346. Forest never engaged in joint settlement negotiations with multiple Generic Manufacturers.

Defendants’ Evidence: Ex. 340, Agovino Dep. 80:12-81:1, 147:13-16.

347. Forest refused to offer any earlier entry date than three months prior to patent expiration including any regulatory exclusivities to any Generic Manufacturer.

Undisputed Record Evidence: Ex. 329, Silber (Mylan) Dep. 26:5-11.

Defendants’ Evidence: Ex. 339, Ryan (Sep. 7) Dep. 200:5-15, 209:2-9; Ex. 340, Agovino Dep. 75:19-76:6; Ex. 34, KE00000169 (“As discussed, Forest and Merz are unwilling to pay Apotex, a non-first filer, any attorney’s fees. They are unwilling to allow any first filer to launch more than 3 months before the patent expires, so are even less willing to allow a non-first-filer to do so.”).

**D. Settlements were in Each Generic Defendant's Individual Best Interest**

348. Each Generic Manufacturer desired to launch its generic Namenda product as early as possible and the Generic Entry Early Acceleration Clause permitted each first-filing Generic Manufacturer to enter as early as any other generic manufacturer.

Undisputed Record Evidence: Ex. 331, Rabinovic (Teva) Dep. 42:24-43:12; Ex. 328, McCormick (DRL) Dep. 157:4-24; Ex. 327, Gupta (Amneal) Dep. 118:17-25; Ex. 330, Nadkarni (Sun) Dep. 127:14-18; Ex. 351, Venkatesan (Wockhardt) Dep. 168:22-169:3.

Defendants' Evidence: Ex. 29, FRX-AT-00000001 at 0023-0024 §§ 4.3-4.5; Ex. 27, FRX-AT-00000038 at 0061 §§ 4.3-4.5; Ex. 25, FRX-AT-00000076 at 0098 §§ 4.3-4.5; Ex. 26, FRX-AT-00000112 at 0134 §§ 4.3-4.5; Ex. 24, FRX-AT-00000148 at 0169-0170 §§ 4.3-4.5; Ex. 28, FRX-AT-00000184 at 0207 §§ 4.3-4.5; Ex. 22, FRX-AT-00000218 at 0239-0240 §§ 4.3-4.5; Ex. 31, FRX-AT-00000340 at 0364 §§ 4.3-4.5; Ex. 32, FRX-AT-00000380 at 0403 §§ 4.3-4.5; Ex. 33, FRX-AT-00000428 at 0450-0451 §§ 4.3-4.5.

349. First filing exclusivity is valuable to generic manufacturers because it provides generic manufactures with a first mover advantage.

Plaintiffs' Admissions. Ex. 189, FRX-AT-01775574, Berndt (NYAG) Decl. ¶ 18 (describing first mover advantage and noting, "Thus, the right to be the exclusive generic for a 180-day period is a valuable one.").

350. Because of the first mover advantage, the first generic manufacturer (or cohort of generic manufacturers) is able to capture and maintain a large share of the market.

Plaintiffs' Admission: Ex. 349, Berndt Dep. 214:25-216:3 ("But first mover advantage typically means that, that you can capture more market share if you're the first entrant.").

Public Sources. Federal Trade Commission, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* 103-04 (August 2011).

351. Each Generic Entry Early Acceleration Clause was valuable to each of the Generic Manufacturers.

Defendants' Evidence: Ex. 194, FRX-AT-03626446 at 6447 (“USL would like ‘most-favored nation’ status for clauses pertaining to pre-booking activities in Sec. 2.2. . . . USL’s view is that we cannot be at a competitive disadvantage to other defendants who settle.”).

Undisputed Record Evidence: Ex. 328, McCormick (DRL) Dep. 157:4-13; Ex. 327, Gupta (Amneal) Dep. 118:17-119:4; Ex. 330, Nadkarni (Sun) Dep. 127:23-128:7; Ex. 331, Rabinovic (Teva) Dep. 42:24-44:17.

352. Each Generic Entry Early Acceleration Clause was included in the settlement agreements at the demand of the Generic Manufacturers.

Defendants' Evidence: Ex. 339, Ryan (Sep. 7) Dep. 202:10-203:11 (“Q. When you say they demand it, was it your expectation that there were generics that would not have settled the patent litigation without those most favored nation clauses? . . . A. I don’t think any of them would have settled without it.”), 251:13-252:10, Ex. 367, Ryan (Nov. 7) Dep. 375:22-376:16 (“The generics require a most favored nation clause.”); Ex. 340, Agovino Dep. 160:24-161:6 (“Q. Why did the settlement agreements with the Namenda first filers include acceleration provisions? A. The generic companies wouldn’t have settled without those provisions.”); Ex. 194, FRX-AT-03626446 at 6447 (“USL would like ‘most-favored nation’ status for clauses pertaining to pre-booking activities in Sec. 2.2. . . . USL’s view is that we cannot be at a competitive disadvantage to other defendants who settle.”).

Undisputed Record Evidence: Ex. 328, McCormick (DRL) Dep. 157:4-13 (“Q. So Dr. Reddy’s got the MFN – most favored nations, with the respect to the launch date, is that right? A. Yes. Q. Would there be a reason for Dr. Reddy’s not to expect that other generic companies would want the same thing? A. Of course everyone wants the best term for themselves.”); Ex. 331, Rabinovic (Teva) Dep. 43:14-44:12 (“[W]e would want to have [a Generic Entry Early Acceleration] provision[] in a settlement agreement because . . . we’d want to make sure that we were getting as good a deal as anybody else was.”).

353. Dr. Fowdur’s economic analysis that the settlement agreements were in each Generic Manufacturer’s independent self-interest stands un rebutted, as none of Plaintiffs’ experts have analyzed the issue.

Defendants' Evidence: Ex. 54, Fowdur Rep. ¶¶ 83-84.

Plaintiffs' Admissions: Ex. 335, Elhauge (Sept. 29) Dep. 39:16-19 (“Q. You are offering no opinion on whether there was an overarching conspiracy between Forest and all of the generics. Correct? A. Correct.”).

**E. No Motive for Generic Defendants to Conspire**

354. Each Generic Manufacturer was able to secure the earliest entry date Forest would have been willing to prove through unilateral negotiation of a Generic Entry Early Acceleration Clause.

Undisputed Record Evidence: Ex. 328, McCormick (DRL) Dep. 152:20-153:8, 157:4-24; Ex. 329, Silber (Mylan) Dep. 93:3-8; Ex. 331, Rabinovic (Teva) Dep. 42:24-45:5; Ex. 352, Gupta (Torrent) Dep. 60:12-15; Ex. 351, Venkatesan (Wockhardt) Dep. 159:2-160:4, 168:22-169:3; Ex. 334, Wilk (Orgenon) Dep. 210:8-12; Ex. 327, Gupta (Amneal) Dep. 118:17-119:19; Ex. 330, Nadkarni (Sun) Dep. 127:14-18, 129:18-131:3.

Defendants' Evidence: Ex. 340, Agovino Dep. 80:12-81:1 (“Q. Mr. Agovino, how is the effect of this provision any different than Forest negotiating jointly with more than one generic? ... A. The difference is that these were terms that were finalized, and each company, each generic company separately negotiated these very vigorously. And it's very different than putting people in the same room. This was used if, for example, they wanted to know did you give a launch date that was earlier to someone else, and we said – we would have to say no, we didn't.”), 147:13-16; Ex. 29, FRX-AT-00000001 at 0023-0024 §§ 4.3-4.5; Ex. 27, FRX-AT-00000038 at 0061 §§ 4.3-4.5; Ex. 25, FRX-AT-00000076 at 0098 §§ 4.3-4.5; Ex. 26, FRX-AT-00000112 at 0134 §§ 4.3-4.5; Ex. 24, FRX-AT-00000148 at 0169-0170 §§ 4.3-4.5; Ex. 28, FRX-AT-00000184 at 0207 §§ 4.3-4.5; Ex. 22, FRX-AT-00000218 at 0239-0240 §§ 4.3-4.5; Ex. 31, FRX-AT-00000340 at 0364 §§ 4.3-4.5; Ex. 32, FRX-AT-00000380 at 0403 §§ 4.3-4.5; Ex. 33, FRX-AT-00000428 at 0450-0451 §§ 4.3-4.5.

355. The Generic Entry Early Acceleration Clause made each generic manufacturer indifferent to the entry dates negotiated by any other generic manufacturer.

Undisputed Record Evidence: Ex. 331, Rabinovic (Teva) Dep. 43:17-44:12 (“Q. Including these provisions in the patent settlement is in Teva's independent self-interest. Correct? ... A. I mean, from a business perspective, I would ... want to have these provisions in a settlement agreement because we're settling the case. There were other filers, and so we'd want to make sure that we were getting as good a deal as anybody else was. So my business is going to have a really hard time accepting an agreement where I'm not allowed to go to market even though somebody else got that right to go to the

market.”); Ex. 327, Gupta (Amneal) Dep. 118:17-119:7 (“Q. You do understand Section 4.3 as well as 4.4. and 4.5 to be MFN clauses or acceleration clauses? A. Yes, I do understand acceleration clauses. Q. And that means if any other generic is able to launch, the entry date for Amneal accelerates to that date, right? A. That’s correct. Q. Including a provision like this in the settlement agreement is in Amneal’s independent best interest; is it not? A. Yes. Q. Because it assures that Amneal has the earliest entry possible, correct? A. That’s correct.”); Ex. 330, Nadkarni (Sun) Dep. 127:23-128:7; Ex. 351, Venkatesan (Wockhardt) Dep. 168:22-169:3 (“Q. Any other reasons why the launch date was important to Wockhardt; did they want to assure they would launch at the earliest date possible? ... A. Yes.”).

#### **F. The Generic Entry Early Acceleration Clauses Ensured Substantial Generic Entry**

356. The Generic Entry Early Acceleration Clause ensured competition amongst the first filing Generics Manufacturers should any generic have negotiated an earlier settlement entry date.

Plaintiffs’ Admissions: Ex. 335, Elhauge (Sep. 29) Dep. 91:14-21 (noting that the contingent entry clauses would have accelerated entry for all generic manufacturers); Ex. 121, Elhauge Rep. I ¶¶ 8-9 (“Because of the contingent entry clauses, if Mylan continued to litigate the patent and won, it could cause many generics to enter the Namenda market, eliminating the vast majority of Forest’s brand profits for Namenda.”); Ex. 193, Lamb Rep. I ¶ 129 (basing his damages claim on the fact that several generic manufacturers would have been able to launch with Mylan, which is a result of the most favored nation provision).

Defendants’ Evidence: Ex. 54, Fowdur Rep. ¶ 76.

357. If triggered, the Generic Entry Early Acceleration Clauses would result in procompetitive effects.

Plaintiffs’ Admissions: Ex. 121, Elhauge Rep. I ¶ 8; Ex. 335, Elhauge (Sep. 29) Dep. 91:14-21, Ex. 368 337:4-11 (agreeing that it is not his position that “when it comes to the first-filers other than Mylan” the Generic Entry Early Acceleration Clause was not a reverse payment); Ex. 193, Lamb Rep. I ¶ 129 (basing his damages claim on the fact that several generic manufacturers would have been able to launch with Mylan, which is a result of the most favored nation provision).

Defendants' Evidence: Ex. 54, Fowdur Rep. ¶¶ 76-77.

**V. HARD SWITCH: NO ANTITRUST INJURY**

**A. The June 2013 Launch of Namenda XR**

358. Forest launched Namenda XR on June 13, 2013.

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op. at ¶ 52.

Defendants' Evidence: Ex. 14, FRX-AT-01909674.

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count One at ¶ 14.

359. Forest invested approximately \$175 million in developing Namenda XR, the “improved version of Namenda,” in a once-daily extended release formulation to conform to prescribers' preferences for once-a-day treatments for Alzheimer's patients.

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op. at ¶¶ 45-46.

Defendants' Evidence: Ex. 11, Meury (NYAG) Decl. at ¶¶ 6, 8.

360. Once-a-day versions for all other FDA approved products for the treatment of Alzheimer's Disease had previously released by June 2013.

Defendants' Evidence: Ex. 321, Ferris Dep., FRX-AT-01732986 at 107:16-109:9; Ex. 323, Reisberg (NYAG) Dep. at 165:23-166:8.

361. Alzheimer's caregivers “viewed Namenda XR as a ‘meaningful and welcome improvement’ over the twice-a-day Namenda IR tablets” in surveys taken during the time period surrounding launch.

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op. at ¶ 50.

Defendants' Evidence: Ex. 196, FRX-AT-01769199.

362. “A manufacturer may aggressively promote and market the new drug or reduce its price to encourage voluntary switching. This has been termed a ‘soft switch.’”

Undisputed Record Evidence: *In re Namenda Antitrust Litig.*, Mem. And Order Den. Def.’s Mot. to Dismiss, No. 15-07488, Dkt. No. 106, at \*8 (S.D.N.Y. Sept. 13, 2016).

Plaintiffs’ Admissions: Ex. 357, Doud (Rochester Drug Co.) Dep. 17:22-18:8 (“What we’re contending is that Forest backed off the promotion of IR in order to further push the XR on Alzheimer’s patients.”).

363. As part of the Namenda XR launch, Forest aggressively promoted and marketed Namenda XR, spending “\$120 million educating patients, caregivers, health care providers, and pharmacists about Namenda XR, including Namenda XR’s benefits and FDA-approved instructions for transitioning from Namenda IR to Namenda XR.”

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op. at ¶ 53.

Defendants’ Evidence: Ex. 197, FRX-AT-01765922 at 5942-5944; Ex. 196, FRX-AT-01769199; Ex. 198, FRX-AT-01779957 (Hausman (NYAG) Decl.) ¶ 22; Ex. 199, FRX-AT-01764620 at 4625.

Plaintiffs’ Admissions: Ex. 357, Doud (Rochester Drug Co.) Dep. 169:18-22 (“Q: And, in your experience, when brand pharmaceutical companies focus on promoting one drug versus another, sales of the drug that they’re focused on promoting tend to increase, correct? A: Absolutely.”).

364. Part of this aggressive promotional effort was the deployment of “1500 experienced sales reps, as well as an informative campaign including journal advertising, direct mail, and physician promotional.”

Plaintiffs’ Admissions: Ex. 358, Benton (Smith Drug Co.) Dep. 257:7-261:5 (discussing Ex. 200, Benton Ex. 21).

365. Part of this aggressive promotional effort was the inclusion of advertising in the wholesalers’ circulars to pharmacists, for which wholesalers were compensated.

Plaintiffs' Admissions: Ex. 358, Benton (Smith Drug Co.) Dep. 257:7-261:5 (discussing Ex. 200, Benton Ex. 21) (“Q. Did Smith Drug select the advertisements that it would include in The DrugSmith? A. Again, I don’t do that, but I would think we select what goes in our DrugSmith program. Q. And Smith Drug wouldn’t market or advertise a drug that it didn’t think was beneficial to patients or its customers, right? ... A. I would think we wouldn’t do it unless we were compensated for it.”).

366. Part of this aggressive promotional effort was a change in how Forest compensated its sales force members; in December 2013, Forest reduced employee incentives to promote Namenda IR, expanded the size of the Namenda XR sales force, and increased the member compensation for Namenda XR conversions.

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op.at ¶ 94.

Defendants' Evidence: Ex. 359, Devlin Dep. 173:24-178:4; Ex. 201, FRX-AT-01775242.

#### **B. Favorable Formulary Placement for Namenda XR**

367. More than 80% of prescription drug expenditures in the United States are paid for by third-party payors (primarily health plans), which “pay all or part of the costs of a prescription drug on behalf of patients.”

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op. at ¶¶ 16-21, 95.

Defendants' Evidence: Ex. 15, Kolassa (Oct. 21, 2014) Decl. ¶ 31; Ex. 202, FRX-AT-01777507 at 7509.

Publicly Available Sources: GAO, No. 13-176, Prescription Drugs: The Number, Role, and Ownership of Pharmacy Services Administrative Organizations, at 9 (Jan. 2013) <http://www.gao.gov/assets/660/651631.pdf> (“Third-party payers accounted for almost 80 percent of drug expenditures in 2010, which represents a significant shift from 30 years ago when payment from individual consumers accounted for the largest portion of expenditures.”).

368. To manage their costs, health plans “shift” demand to the drugs that they prefer consumers purchase by “generat[ing] a drug formulary, a list of approved drugs that will be paid for by the health plan (in whole or in part) when an insured patient fills a prescription.”

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op. at ¶¶ 16-21, 95; Ex. 360, Lahman (Optum) Dep. 47:7-48:20 (discussing how a third-party payor can “use its formularies in order to shift market share from one drug to another within a given class”).

Plaintiffs’ Admissions: Ex. 357, Doud (Rochester Drug Co.) Dep. 141:21-142:8; Ex. 358, Benton (Smith Drug Co.) Dep. 242:9-14; 243:3-9; Ex. 349, Berndt Dep. 187:8-190:14 (discussing the role of drug formularies and the process of tiering).

369. Health plans often pair the drug formulary with a system of co-payments (“co-pays”), which steer physicians and patients towards either generic drugs (which are usually on “Tier 1” of a formulary) or “preferred brand” drugs (which are usually on “Tier 2” of a formulary) by offering lower out-of-pocket prices.

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op. at ¶¶ 16-21, 95; Ex. 360, Lahman (Optum) Dep. 47:7-50:14 (discussing the use of copay differentials and tiering to “drive patient to use the tier 1 drugs, rather than the higher tier drugs”).

Plaintiffs’ Admissions: Ex. 349, Berndt Dep. 187:8-190:14.

370. Patients will pay higher prices for a drug, in the form of higher “co-pays,” if a pharmaceutical drug is on “Tier 3” of a formulary. Moreover, health plans may impose additional requirements, called “step edits,” that require patients to try drugs on lower tiers before authorizing the use of a “Tier 3” drug.

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op. at ¶¶ 16-21, 95; Ex. 360, Lahman (Optum) Dep. 45:18-47:6; 53:15-55:19.

Defendants’ Evidence: Ex. 198, Hausman (NYAG) Decl. ¶ 13, Ex. 203, FRX-AT-01776549 ¶¶ 16-17 (discussing “utilization management tools” which “are instituted in

an attempt to maximize the possibility that covered drugs are appropriately utilized”); Ex. 359, Devlin Dep. 235:9-236:16.

Plaintiffs’ Admissions: Ex. 349, Berndt Dep. 187:8-190:14 (noting that “various utilization tools” including “steps edits [and] prior authorizations” favor lower tier products over higher tier ones).

371. Forest undertook extensive negotiations with multiple health plans to obtain “preferred brand” status for Namenda XR on the health plan’s Medicare Part D and commercial drug formularies, so that patients who wished to try Namenda XR did not face obstacles, like tiering or step edits, in doing so.

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op. at ¶¶ 19-21, 95; Ex. 360, Lahman (Optum) Dep. 83:2-84:3; 86:1-87:23; 94:13-95:5 (discussing the Forest negotiations with Optum).

Defendants’ Evidence: Ex. 198, Hausman (NYAG) Decl. ¶ 13; Ex. 11, Meury (NYAG) Decl. ¶ 12; Ex. 209, FRX-AT-01777928 (BlueCross BlueShield of North Carolina Evidence of Coverage Formulary); Ex. 210, FRX-AT-01778283 (CareMore 2015 Formulary); Ex. 211, FRX-AT-01778355 (WellCare 2015 Comprehensive Formulary); Ex. 212, FRX-AT-01778462 (Blue Shield of California Medicare Basic Plan 2015 Formulary); Ex. 213, FRX-AT-01778527 (Gundersen Health Plan Senior Preferred HMO 2015 Formulary); Ex. 214, FRX-AT-01778633 (HAP Medicare Solutions 2015 Formulary); Ex. 215, FRX-AT-01778749 (Horizon Medicare Blue Patient-Centered w/RX (HMO) 2015 Formulary); Ex. 216, FRX-AT-01778879 (Network Health 2015 Part D Formulary); Ex. 217, FRX-AT-01779008 (Humana 2015 Prescription Drug Guide); Ex. 218, FRX-AT-01779208 (HealthNet Cal MediConnect Plan 2015 List of Covered Drugs); Ex. 359, Devlin Dep. 136:7-25; 233:16-237:6; 260:25-262:17.

Plaintiffs’ Admissions: Ex. 349, Berndt Dep. 187:8-190:14.

372. Forest also view “preferred brand” placement on health plan formularies as essential for drug adoption, since the failure to place a drug on the “preferred brand” tier significantly hinders the overall pool of patients that can access the drug at comparable prices.

Defendants’ Evidence: Ex. 219, FRX-AT-03793470, at 3479 (“Better access: Needed to make sure most patients would not pay more for Namenda XR.”); Ex. 359, Devlin Dep. 233:16-237:6; Ex. 54, Fowdur Rep. App’x. A ¶ 16 (“Data from Forest indicates the date

that each plan added Namenda XR onto its formulary and hence these dates in combination with the enrollment data provide a monthly benchmark for covered lives with access to Namenda XR on a preferred-brand tier.”).

Undisputed Record Evidence: Ex. 360, Lahman (Optum) Dep. 45:18-47:6.

Plaintiffs’ Admissions: Ex. 349, Berndt Dep. 187:8-190:14.

373. As of July 1, 2013, Namenda XR had Medicare Part D formulary coverage for six of the nation’s top ten Medicare Part D health plans, and two of the top ten commercial health plans.

Defendants’ Evidence: Ex. 220, FRX-AT-03864752 at 4807; Ex. 54, Fowdur Rep. ¶¶ 105-06 (attesting that roughly 75% of Namenda XR sales depended on Medicare formulary placement).

374. By January 1, 2014, nine of the nation’s top health plans had added Namenda XR to the “preferred brand access” tier of their Medicare Part D formularies; these additions resulted in Namenda IR and XR being placed on the same tier for 78.5% of all Medicare Part D prescriptions.

Defendants’ Evidence: Ex. 221, FRX-AT-01734505 at 4509 (“With these changes, Namenda XR will have Preferred Brand formulary access to over 26 million Part D patients, bringing our total Medicare Preferred Brand formulary access from 53% to 80%. This significantly increased access represents a tremendous opportunity for Forest to exceed our conversion goals for Namenda XR.”); Ex. 223, FRX-AT-03685981 (listing total prescriptions with preferred access at 78.5%); Ex. 222, FRX-AT-01615958 at -5961 (“Very good week for XR . . . The increase is most likely due to increased conversion, perhaps a strong signal of the impact of the formulary wins.”).

375. Forest achieved similar results for formulary placement on these same health plans’ commercial formularies.

Defendant’s Evidence: Ex. 224, FRX-AT-03815141 (listing the formulary coverage for all health care plans including the Tier 2 status on payors like Aetna, Humana, Cigna, Express Scripts and others); see generally Ex. 209, FRX-AT-01777928; Ex. 210, FRX-

AT-01778283; Ex. 211, FRX-AT-01778355; Ex. 212, FRX-AT-01778462; Ex. 213, FRX-AT-01778527; Ex. 214, FRX-AT-01778633; Ex. 215, FRX-AT-01778749; Ex. 216, FRX-AT-01778879; Ex. 217, FRX-AT-01779008; Ex. 218, FRX-AT-01779208; Ex. 225, FRX-AT-01834249.

**C. Namenda XR Priced at a Discount to Namenda IR**

376. To achieve its goal of comparable formulary coverage to Namenda IR (i.e. comparable “preferred brand” tier placement across all major Medicare Part D and Commercial formularies), Forest aggressively discounted Namenda XR in negotiations with health plans.

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op. at ¶ 97.

Defendants’ Evidence: Ex. 198, FRX-AT-01779957; Ex. 226, FRX-AT-01737553 at 22:6-23:20; Ex. 362, FRX-AT-01732297, Kane Dep. 276:11-277:4; Ex. 359, Devlin Dep. 234:18-235:1, 236:17-237:6, 261:14-262:17;

Plaintiffs Admissions: Ex. 363, Lamb (Oct. 6) Dep. 158:9-159:9; DPPs’ Statement of Material Facts ISO Count One at ¶ 115.

377. For many health plan and pharmaceutical benefits manager, Forest set Namenda XR’s Wholesale Acquisition cost at 5% less than Namenda IR.

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op. at ¶ 96.

Defendants’ Evidence: Ex. 11, Meury (NYAG) Decl. ¶ 12; Ex. 224, FRX-AT-03815141 (listing the formulary coverage for all health care plans for Namenda XR).

378. For most major health plans, Forest discounted Namenda XR even further. “On average, Namenda XR was sold at a 16% discount compared to Namenda IR.”

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op. at ¶ 96.

Defendants’ Evidence: Ex. 226, FRX-AT-01737553 at 22:3-25:1 (noting that “the health plans demand[ed] a discount . . . for every product and they have a great deal of leverage”); Ex. 11, Meury (NYAG) Decl. ¶ 12; Ex. 359, Devlin Dep. 233:19-234:17

(explain that Forest had “to negotiate and discount [its] price [for health plans], and those companies are very formidable negotiators. That’s their sole job is to negotiate the lowest price possible for them and the highest discounts or rebates back from the manufacturer.”).

379. For larger formularies, including Optum (which constituted over 20% of the Medicare Part D marketplace), discounts ranged from [REDACTED] to over [REDACTED].

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op. at ¶ 96-97 (“Discounts that Forest offered ranged anywhere from [REDACTED]. For example, one of the largest providers of the Medicare Part D benefit in the country secured a discount of over [REDACTED]. . . The total discounts given by Forest exceed \$200 million.”) (citing testimony from Bill Meury and Mark Devlin); see also Ex. 224, FRX-AT-03815141 (listing the formulary coverage for all health care plans including the Tier 2 status on payors like Aetna, Humana, Cigna, Express Scripts and others); Ex. 360, Lahman (Optum) Dep. 81:7-10 (“Q: Okay. Okay. And then for Namenda XR it refers to a rebate amount of [REDACTED], correct? A: Correct.”).

#### **D. Projected Conversion Rates**

380. Since Forest lacked Namenda XR sales data before the drug launched, Forest informed its decision making by considering several analogous launches for other extended release products that had been launched.

Defendants’ Evidence: Ex. 359, Devlin Dep.86:23-88:19 (discussing FRX-AT-01657071); 93:15-20; 90:16-23 (noting that Forest created “analogue analysis” using IMS NPA data before having market data), 137:1-24; Ex. 325, Snyder Dep 81:24-82:14 (describing the process for building Forest’s early Namenda XR forecasts as “look[ing] at, you know epidemiology data for baby boomers”); Ex. 227, FRX-AT-01657071; Ex. 370, FRX-AT-04134771 (discussing various analogues for Namenda XR launch).

Plaintiffs’ Admissions: Ex. 349, Berndt Dep. 163:5-19 (“I believe Ms. Snyder said that they used a lot of historical analogues in creating their forecasts, and most of those historical analogues had been promoted with soft switch tactics because the number of hard switches that had actually occurred before 2013 was minimal.”).

381. Depending on which analogues were considered, estimates of patient conversion to Namenda XR varied; several models of analogues anticipated conversion to be in the mid-thirties at 12 months, with others predicting conversion in the mid-forties by 24 months.

Defendants' Evidence: Ex. 228, FRX-AT-01783541; Ex. 229, FRX-AT-01832055; Ex. 230, FRX-AT-01657074.

382. In some instances, comparison of analogous launches using “soft switch” marketing efforts yielded a range of outcomes as high as 69% conversion for Namenda XR.

Defendants' Evidence: Ex. 227, FRX-AT-01657071; Ex. 229, FRX-AT-01832055.

383. Having reviewed prior launches (for pricing, formulary placement, expected consumer and physician reaction, and other considerations), Forest began attempting to estimate the likely rate of conversion for both new and existing patients switching from Namenda IR to Namenda XR.

Plaintiffs' Admissions: Ex. 231, Berndt Rep. I Ex. D.

Defendants' Evidence: Ex. 232, FRX-AT-01595859 (Forecast originally created in 1/28/2007); Ex. 233, FRX-AT-01671051 (same); Ex. 234, FRX-AT-01614825 (same); Ex. 235, FRX-AT-01618974(same); Ex. 236, FRX-AT-03727191 (same); Ex. 237, FRX-AT-01613386 (same); *see also* Ex. 227, FRX-AT-01657071; Ex. 238, FRX-AT-01639598; Ex. 239, FRX-AT-01612936; Ex. 240, FRX-AT-01612940; Ex. 241, FRX-AT-01608706; Ex. 242, FRX-AT-01639602; Ex. 243, FRX-AT-00952900; Ex. 244, FRX-AT-03769058; Ex. 247, FRX-AT- 3725539; Ex. 251, FRX-AT-01656854; Ex. 252, FRX-AT-01619281; Ex. 253, FRX-AT-01639600; Ex. 254, FRX-AT-01614824; Ex. 255, FRX-AT-01813893; Ex. 256, FRX-AT-01655251; Ex. 257, FRX-AT-01613917; Ex. 258, FRX-AT-01611806; Ex. 259, FRX-AT- 3727529; Ex. 260, FRX-AT-03793457; Ex. 261, FRX-AT-03727794; Ex. 262, FRX-AT-03727831; Ex. 263, FRX-AT-03729066; Ex. 264, FRX-AT-03731393; Ex. 265, FRX-AT-03732732; Ex. 266, FRX-AT-03734393; Ex. 248, FRX-AT-01752159.

384. On November 19, 2012, Forest prepared the first iteration of its Namenda XR conversion forecast that would be adjustable based on Forest's understandings about the products launch.

Defendants' Evidence: Ex. 267, FRX-AT-01774559 (per the document's metadata).

385. That forecast – and its later iterations - contain numerous assumptions, including: (a) the date of Namenda XR Launch; (b) the rate of conversion by Long Term Care facilities from Namenda IR to Namenda XR; (c) the rate of conversion by non-Long Term Care purchasers from Namenda IR to Namenda XR; (d) the date (if applicable) for Namenda IR withdrawal; (e) the anticipated launch date of Forest's Fixed Dose Combination product (which contained Namenda XR and generic Donepezil); (f) the pricing of Namenda IR, Namenda XR, and the Fixed Dose Combination; (g) the anticipated date of entry for generic Namenda IR; (h) the anticipated rate of erosion for branded Namenda IR due to the entry of generic Namenda IR and (i) the anticipated rate of erosion for branded Namenda XR due to the entry of generic Namenda IR.

Defendants' Evidence: Ex. 267, FRX-AT-01774559 (on table labeled "Namenda Monthly\_Conventional," beneath heading labeled "assumptions "); *see also* Ex. 239, FRX-AT-01612936, Ex. 244, FRX-AT-03769058; Ex. 245, FRX-AT-01671038; Ex. 246, FRX-AT-01671046; Ex. 247, FRX-AT-03725539; Ex. 233, FRX-AT-01671051; Ex. 248, FRX-AT-01752159.

386. As Forest began to build out these forecasts with increased frequency and an improved understanding of Namenda XR's actual sales trends, Forest's forecasts continued to predict a range of outcomes with several reaching 40% conversion using only soft switch marketing efforts.

Plaintiffs' Admissions: Ex. 231, Berndt Rep. I Ex. D.

Defendants' Evidence: Ex. 232, FRX-AT-01595859, Ex. 233, FRX-AT-01671051, Ex. 234, FRX-AT-01614825; Ex. 235, FRX-AT-01618974, Ex. 236, FRX-AT-03727191 (same), Ex. 237, FRX-AT-01613386 (same), Ex. 239, FRX-AT-01612936, Ex. 244, FRX-AT-03769058, Ex. 245, FRX-AT-01671038; Ex. 246, FRX-AT-01671046; Ex. 247, FRX-AT-03725539; Ex. 233, FRX-AT-01671051; Ex. 248, FRX-AT-01752159.

387. At least one Forest forecast modeled conversion to be in the 55% range at the 24 month mark.

Plaintiffs Admissions: Ex. 231, Berndt Rep. I ¶ 46, n. 84

Defendants' Evidence: Ex. 249, FRX-AT-01602903; *see also* Ex. 250, FRX-AT-01630867 at 0871 ("We have every reason to believe we can convert 40 or even 50 percent of Namenda IR").

388. Forecasts dated after the launch of Namenda XR in June 2013 reflect a narrower band of conversion expectations with several still predicting conversion in the 40% range at the end of 19 months.

Plaintiffs Admissions: Ex. 231, Berndt Rep. I Ex. D.

Defendants' Evidence: Ex. 268, FRX-AT-01642799; Ex. 232, FRX-AT-01595859; Ex. 269, FRX-AT-01592880; Ex. 270, FRX-AT-01644132; Ex. 271, FRX-AT-01616631; Ex. 272, FRX-AT-01655656; Ex. 273, FRX-AT-01617447; Ex. 274, FRX-AT-03724272; Ex. 275, FRX-AT-01618023; Ex. 276, FRX-AT-03724325; Ex. 277, FRX-AT-01639601; Ex. 278, FRX-AT-03600941; Ex. 279, FRX-AT-01639599; Ex. 280, FRX-AT-01601242; Ex. 238, FRX-AT-01639598; Ex. 239, FRX-AT-01612936; Ex. 240, FRX-AT-01612940; Ex. 233, FRX-AT-01671051; Ex. 241, FRX-AT-01608706; Ex. 242, FRX-AT-01639602; Ex. 243, FRX-AT-00952900; Ex. 244, FRX-AT-03769058; Ex. 247, FRX-AT-03725539; Ex. 251, FRX-AT-01656854; Ex. 252, FRX-AT-01619281; Ex. 253, FRX-AT-01639600; Ex. 254, FRX-AT-01614824; Ex. 255, FRX-AT-01813893; Ex. 256, FRX-AT-01655251; Ex. 234, FRX-AT-01614825; Ex. 257, FRX-AT-01613917; Ex. 235, FRX-AT-01618974; Ex. 236, FRX-AT-03727191; Ex. 258, FRX-AT-01611806; Ex. 259, FRX-AT-03727529; Ex. 237, FRX-AT-01613386; Ex. 281, FRX-AT-01639171; Ex. 260, FRX-AT-03793457; Ex. 261, FRX-AT-03727794; Ex. 262, FRX-AT-03727831; Ex. 263, FRX-AT-03729066; Ex. 264, FRX-AT-03731393; Ex. 265, FRX-AT-03732732; Ex. 266, FRX-AT-03734393; Ex. 248, FRX-AT-01752159.

389. By October 10, 2013, with Forest having three months of actual data on conversions post-launch, those forecasts began to land consistently in the range of 40% conversion at the end of approximately 19 months.

Defendants' Evidence: Ex. 238, FRX-AT-01639598; Ex. 239, FRX-AT-01612936; Ex. 240, FRX-AT-01612940; Ex. 233, FRX-AT-01671051; Ex. 241, FRX-AT-01608706; Ex. 242, FRX-AT-01639602; Ex. 243, FRX-AT-00952900; Ex. 244, FRX-AT-03769058; Ex. 247, FRX-AT-03725539; Ex. 251, FRX-AT-01656854; Ex. 252, FRX-AT-01619281; Ex. 253, FRX-AT-01639600; Ex. 254, FRX-AT-01614824; Ex. 255, FRX-AT-01813893; Ex. 256, FRX-AT-01655251; Ex. 234, FRX-AT-01614825; Ex. 257, FRX-AT-01613917; Ex. 235, FRX-AT-01618974; Ex. 236, FRX-AT-03727191; Ex. 258, FRX-AT-01611806; Ex. 259, FRX-AT-03727529; Ex. 237, FRX-AT-01613386; Ex. 281, FRX-AT-01639171; Ex. 260, FRX-AT-03793457; Ex. 261, FRX-AT-03727794; Ex. 262, FRX-AT-03727831; Ex. 263, FRX-AT-03729066; Ex. 264, FRX-AT-03731393; Ex. 265, FRX-AT-03732732; Ex. 266, FRX-AT-03734393; Ex. 248, FRX-AT-01752159.

390. Senior Forest officials discussed PowerPoint slides around mid-October 2013 that projected Forest's soft switch marketing efforts alone would convert 40% of the memantine market to Namenda XR by the launch of generic Namenda IR, and additional information, such as the results of a survey of caregivers, was factored into Forest's forecasts.

Defendants' Evidence: Ex. 282, FRX-AT-04199437 (Meury explaining to members of his team that the Namenda Transition Plan, which estimated conversion at 40% was "what we reviewed today with [Frank Perrier, Forest's CFO] and [Brent Saunders, Forest's CEO]; Ex. 371, FRX-AT-01859720 ("Namenda Franchise: MD and caregiver response to XR is above expectations; Conversion projected to 30%-40%"); *see also* Ex. 283, FRX-AT-03724953 (email to Lei Meng, Forest's director of Global Commercial Assessments, that "the latest" model of Forest's "Namenda Production Forecast" predicts 40% conversion under the conventional scenario); Ex. 372, FRX-AT-01593023 (email dated October 10, between Liz Fung and Bill Meury stating that "[in] the Five-Year Plan we have [Namenda XR conversion under the soft switch] going up to 40%").

391. In the New York Attorney General action, the Court accepted an econometric model constructed by NYAG's economist, Ernst Berndt, the same economist DPPs use here,

based on Forest's own conventional withdrawal forecasts; that model projected Forest's branded memantine products to constitute 40% of the memantine market under a conventional scenario.

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op. at ¶ 139.

Defendants' Evidence: Ex. 284, FRX-AT-01784112.

Plaintiffs' Admissions: Ex. 349, Berndt Dep. 280:24-281:13 (citing Ex. 285, FRX-AT-01736051, and referring to Ex. 286, FRX-AT-01657151 as "[a] model [which] appears repeatedly in various forms in the Forest documents, and one can reasonably select the version of the model that was prepared in approximately November 2013, close in time to (i) the date of the amended IR and XR conversion plan presentation October 2013; and (ii) a board presentation of December 2013 as a sensible indicator of Forest's views.").

#### **E. Actual Conversion Rates**

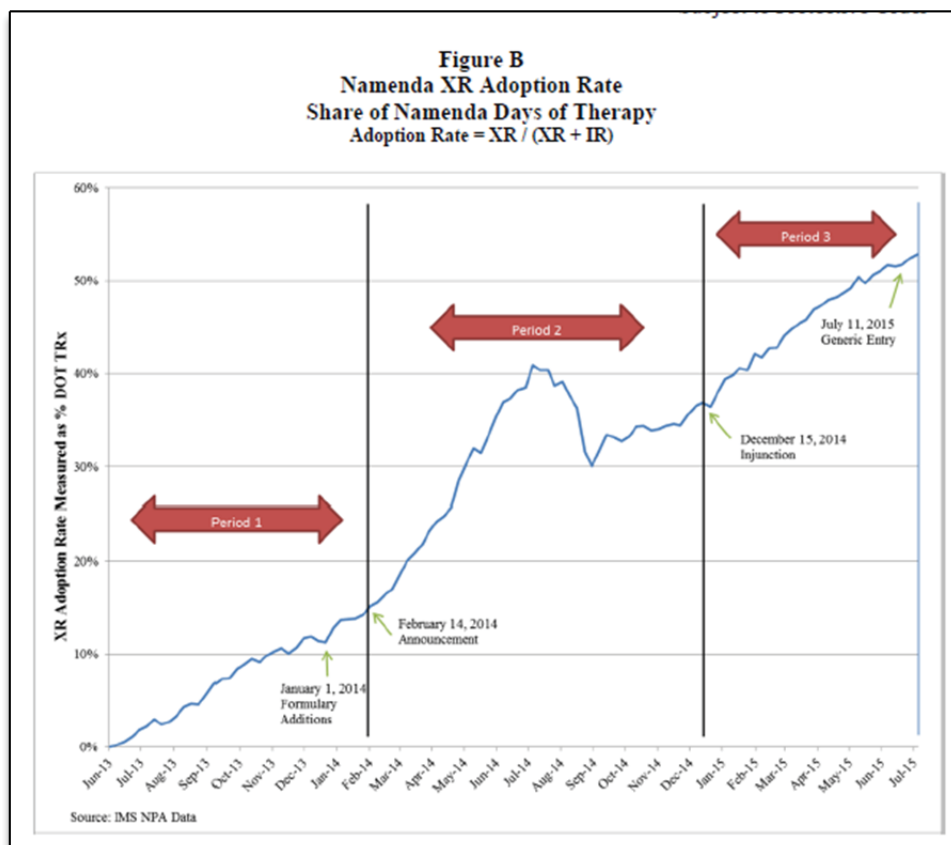
392. Based on the sales data compiled by Plaintiffs' expert, Dr. Russell Lamb, and derived from third-party vendors, Forest's actual sales data were similar to higher-end forecast estimates presented and compiled by Forest personnel.

Defendants' Evidence: Ex. 287, Cremieux Rep. ¶ 50, Fig. 1 (reflecting the results of produced backup data for Plaintiffs' expert Dr. Russell Lamb constructed with IMS NPA data and Forest's internal transaction data).

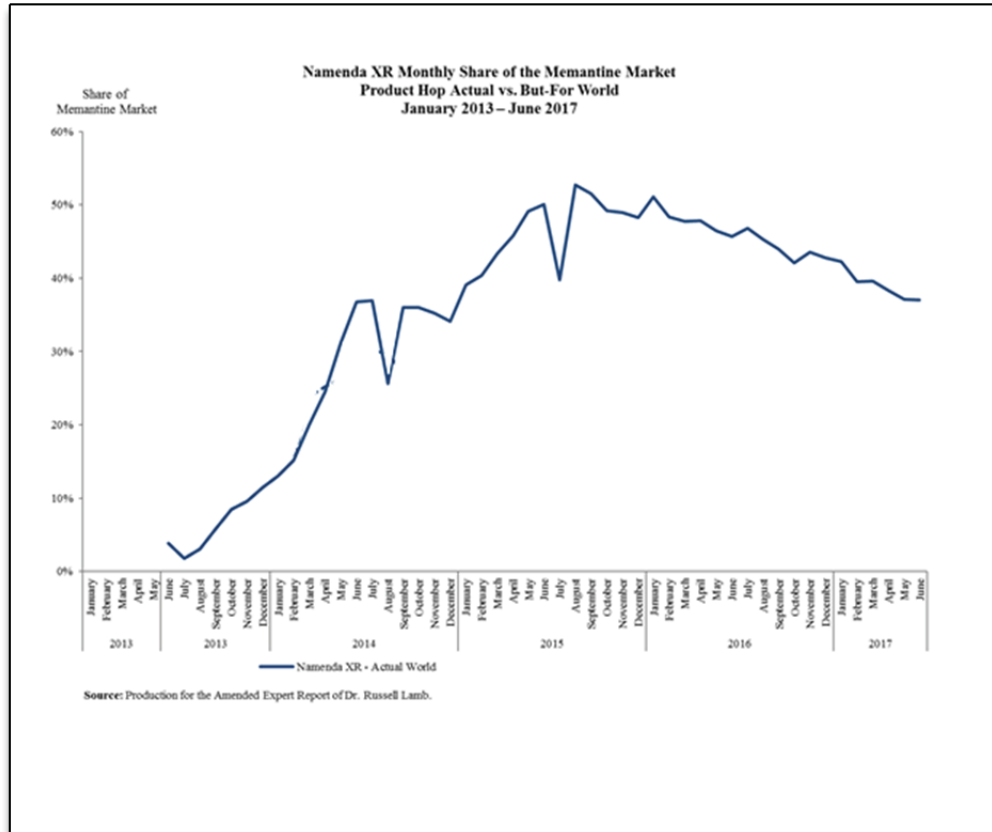
Plaintiffs' Admissions: Ex. 56, Lamb Rep. II ¶ 98, Fig. 4.

393. Using Namenda XR's percent of supply of the memantine market as a measure of "conversion rate," Dr. Lamb's review of Forest's sales transaction data and Dr. Fowdur's review of total days of therapy prescriptions reflects in the following figure.

Defendants' Evidence: Ex. 287, Cremieux Rep. ¶ 50, Fig. 1 (reflecting the results of produced backup data for Plaintiffs' expert Dr. Russell Lamb); Ex. 54, Fowdur Rep. Fig. B.



Plaintiffs' Admissions: Ex. 56, Lamb Reply Rep. ¶ 98, Fig. 4.



394. In June 2014, 12 months after Namenda XR's launch in June 2013, Namenda XR's share of the memantine market in the actual world based on NSP data rose to approximately 36%.

Defendants' Evidence: Ex. 287 Cremieux Rep. ¶ 50, Fig. 1 (reflecting the results of produced backup data for Plaintiffs' expert Dr. Russell Lamb); *see also* Ex. 54, Fowdur Rep. Fig. B (reflecting roughly 36% conversion based on average of weekly NPA data).

Plaintiffs' Admissions: Ex. 56, Lamb Reply Rep. ¶ 98, Fig. 4.

395. In December 2014, 18 months after the Namenda XR's launch in June 2013, Namenda XR's share of the memantine market in the actual world based on NSP data fell to approximately 34%.

Defendants' Evidence: Ex. 287, Cremieux Rep. ¶ 50, Fig. 1 (reflecting the results of produced backup data for Plaintiffs' expert Dr. Russell Lamb); *see also* Ex. 54, Fowdur Rep. Fig. B (reflecting roughly 36% conversion based on NPA data).

Plaintiffs' Admissions: Ex. 56, Lamb Reply Rep. ¶ 98, Fig. 4.

396. Multiple forecasts compiled by Forest (particularly those compiled with roughly 3 months of patient data) predicted that Namenda conversion at 18 months would fall within the range of 30-40%.

Defendant's Documents: Ex. 238, FRX-AT-01639598; Ex. 239, FRX-AT-01612936; Ex. 240, FRX-AT-01612940; Ex. 233, FRX-AT-01671051; Ex. 241, FRX-AT-01608706; Ex. 242, FRX-AT-01639602; Ex. 243, FRX-AT-00952900; Ex. 244, FRX-AT-03769058; Ex. 247, FRX-AT-03725539; Ex. 251, FRX-AT-01656854; Ex. 252, FRX-AT-01619281; Ex. 253, FRX-AT-01639600; Ex. 254, FRX-AT-01614824; Ex. 255, FRX-AT-01813893; Ex. 256, FRX-AT-01655251; Ex. 234, FRX-AT-01614825; Ex. 257, FRX-AT-01613917; Ex. 235, FRX-AT-01618974; Ex. 236, FRX-AT-03727191; Ex. 258, FRX-AT-01611806; Ex. 259, FRX-AT-03727529; Ex. 237, FRX-AT-01613386; Ex. 281, FRX-AT-01639171; Ex. 260, FRX-AT-03793457; Ex. 261, FRX-AT-03727794; Ex. 262, FRX-AT-03727831; Ex. 263, FRX-AT-03729066; Ex. 264, FRX-AT-03731393; Ex. 265, FRX-AT-03732732; Ex. 266, FRX-AT-03734393; Ex. 248, FRX-AT-01752159.

397. On December 15, 2014, Judge Sweet entered a preliminary injunction, which required that Forest "shall continue to make Namenda IR (immediate-release tablets available on the same terms and conditions applicable since July 21, 2013 (the date Namenda XR entered the market)" with which Forest fully complied.

Public Documents: Ex. 288, FRX-AT-01747641, *New York v. Actavis, plc*, No. 1:14-cv-07473 (S.D.N.Y. Dec. 15, 2014), Dkt. 85 ("December 2014 Injunction"); Ex. 291, Settlement Agreement, *New York v. Actavis, plc*, No. 1:14-cv-07473 (S.D.N.Y. Nov. 30, 2015) (ECF No. 96-1) ("Whereas, the injunction prevented Allergan from removing Namenda IR from the market, or limiting the distribution of Namenda IR, and during the Injunction term and afterwards Allergan has continued to manufacture and supply Namenda IR, thus permitting patient access at all times to Namenda IR in all 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, and Guam[.]").

Defendants' Evidence: Ex. 359, Devlin Dep. 238:4-245:6 (discussing Ex. 289, Devlin Ex. 34); Ex. 325, Snyder Dep. 109:11-116:17 (discussing Ex. 290, Snyder Ex. 6)

Plaintiffs' Admissions: Ex. 364, Lamb (Nov. 10, 2017) Dep. at 132:7-18 (acknowledging that Namenda IR remained available for purchase by direct-purchaser plaintiffs at all times prior to generic entry in July 2015).

398. The December 2014 Injunction also required that Forest shall “inform healthcare providers, pharmacists, patients, caregivers, and health plans of this injunction (and provide a copy of the injunction or other means to easily view the injunction) and the continued availability of Namenda IR in the same or substantially similar manner in which they informed them of Defendants’ plan to discontinue Namenda IR in February 2014” with which Forest fully complied.

Undisputed Record Evidence: Ex. 288, FRX-AT-01747641, December 2014 Injunction; Ex. 291, Settlement Agreement, *New York. v. Actavis, plc*, No. 1:14-cv-07473 (S.D.N.Y. Nov. 30, 2015) (ECF No. 96-1) (“Whereas, in December 2014 Allergan informed healthcare providers, pharmacists, patients, caregivers, and health plans of the Injunction and the continued availability of Namenda IR in the same or substantially similar manner in which it announced in February 2014 the potential plan to discontinue Namenda IR[.]”).

Defendants' Evidence: Ex. 359, Devlin Dep. 238:4-245:6 (discussing Ex. 289, Devlin Ex. 34); Ex. 325, Snyder Dep. 109:11-116:17 (discussing Ex. 290, Snyder Ex. 6).

399. The December 2014 Injunction required that Forest “shall not impose a ‘medical necessity’ requirement or form for filling of prescriptions of Namenda IR during the Injunction Term” with which Forest fully complied.

Undisputed Record Evidence: Ex. 288, FRX-AT-01747641, December 2014 Injunction; Ex. 291, Settlement Agreement, *New York. v. Actavis, plc*, No. 1:14-cv-07473 (S.D.N.Y. Nov. 30, 2015) (ECF No. 96-1) (“Whereas, Allergan did not impose a “medical necessity requirement for patients to receive Namenda IR before, during or after the Injunction; Whereas at no time before during or after the Injunction was Namenda IR made unavailable by Allergan or otherwise limited in distribution [.]”).

Defendants' Evidence: Ex. 359, Devlin Dep. 238:4-245:6 (discussing Ex. 289, Devlin Ex. 34); Ex. 325, Snyder Dep. 109:11-116:17 (discussing Ex. 290, Snyder Ex. 6); Ex. 290, October 6, 2015 Declaration of Julie Snyder.

400. During the period between December 2014 and June 2015, Forest undertook steps designed to undo any purported effects of the February 2014 announcement, including posting the December 2014 Injunction to the Namenda website and circulating over 900,000 emails to the caregiver community.

Undisputed Record Evidence: Summary Judgment Mem. Decision and Order, Dkt. 253, at 16; Ex. 291, Settlement Agreement, *New York v. Actavis, plc*, No. 1:14-cv-07473 (S.D.N.Y. Nov. 30, 2015) (ECF No. 96-1) at \*1-2.

Defendants' Evidence: Ex. 359, Devlin Dep. 238:4-245:6 (discussing Ex. 289, Devlin Ex. 34); Ex. 325, Snyder Dep. 109:11-116:17 (discussing Ex. 290, Snyder Ex. 6)

401. In June 2015, 24 months after Namenda XR's launch in June 2013, Namenda XR's share of the memantine market in the actual world based on NSP data rose to approximately 50%.

Defendants' Evidence: Ex. 287, Cremieux Rep. ¶ 50, Fig. 1 (reflecting the results of produced backup data for Plaintiffs' expert Dr. Russell Lamb).

Plaintiffs' Admissions: Ex. 56, Lamb Reply Rep. ¶ 98, Fig. 4.

402. At the time of generic entry in July 2015, the conversion rate of Namenda XR was approximately 53%.

Defendants' Evidence: Ex. 287, Cremieux Rep. ¶ 50, Fig. 1 (reflecting the results of produced backup data for Plaintiffs' expert Dr. Russell Lamb); Ex. 54 Fowdur Rep. ¶ 103, Fig. B (reflecting 52.8% conversion based on weekly NPA data).

Plaintiffs' Admissions: Ex. 56, Lamb Reply Rep. ¶ 98, Fig. 4.

**F. The February 2014 Planned-Withdrawal Announcement**

403. On October 18, 2013, Forest was internally considering withdrawing Namenda IR from the market.

Defendants' Evidence: Ex. 292, FRX-AT-01731312 (Letter, Namenda XR Transition Project Team (Oct. 18, 2013)).

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Opinion, ¶ 75.

404. Forest's CEO Brent Saunders made the final decision to withdraw Namenda IR from the market on February 2014.

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Opinion, ¶ 75.

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count One at 35, ¶ 79.

Defendants' Evidence: Ex. 354, NYAG Saunders Dep. Tr. (Oct. 25, 2014) 321:6-25 ("Q. Who made the decision to discontinue Namenda IR? A. I did. Q. You're saying February 2014 is when the decision was made, is that correct? A. I made the decision. Q. And you made the decision. Was there a meeting that you made the decision at, a telephone call? A. No, we had a series of meetings throughout late 2013 and up until February 14<sup>th</sup> of 2014, this was not a decision we made lightly, we carefully considered it, we studied it. And because we achieved all of our objectives at the time, so we thought, we thought we had the green light to go ahead and do it.")

405. On February 14, 2014, Forest issued a press release publically announcing its plan to focus its manufacturing and marketing efforts on once-a-day Namenda XR and discontinue the sale of Namenda IR tablets effective August 15, 2014 (the "February 2014 Announcement").

Defendants' Evidence: Ex. 293, FRX-AT-01769268 (Press Release, Forest Labs, Forest Laboratories to Discontinue Namenda® Tablets, Focus on Once-Daily Namenda XR® (Feb. 14, 2014)).

Plaintiffs' Admissions: Am. Compl., Dkt. 26, ¶ 174; DPPs' Statement of Material Facts ISO Count One ¶ 15.

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op., ¶ 77 (“On February 14, 2014, Forest began the ‘forced switch’ by publically announcing that Namenda IR tablets would be discontinued on August 15, 2014.”) (citation omitted).

406. The February 2014 Announcement quoted Marco Taglietti, “‘Namenda XR offers important benefits, including convenient, once-daily dosing, which is particularly meaningful for this patient population and their caregivers.’”

Defendants’ Evidence: Ex. 293, FRX-AT-01769268 (Press Release, Forest Labs, Forest Laboratories to Discontinue Namenda® Tablets, Focus on Once-Daily Namenda XR® (Feb. 14, 2014)).

407. The February 2014 Announcement also stated, “Importantly, physicians can switch patients from NAMENDA to NAMENDA XR the very next day without titration, as outlined in the FDA-approved package insert. In addition to its convenient dosing, NAMENDA XR capsules can be opened and the contents sprinkled on applesauce for patients who have difficulty swallowing pills.”

Defendants’ Evidence: Ex. 293, FRX-AT-01769268 (Press Release, Forest Labs, Forest Laboratories to Discontinue Namenda® Tablets, Focus on Once-Daily Namenda XR® (Feb. 14, 2014)).

408. The February 2014 Announcement gave advanced notice to all relevant stakeholders by announcing Forest’s truthful intentions at the time to discontinue its older, twice-a-day tablet product.

Defendants’ Evidence: Defendants’ Response to DPPs’ Statement of Material Facts on Count One, Dkt. 158, at 9.

409. Forest also issued letters communicating its plan to patients, caregivers, health care providers, and various interest groups.

Defendants' Evidence: Ex. 294, FRX-AT-01784874 (Feb. 18, 2014 Letter from Forest to Caregivers); Ex. 295, FRX-AT-01784876 (Feb. 14, 2014 Letter from Forest to Health Care Providers).

Plaintiffs' Admissions: Am. Compl., Dkt. 26, ¶ 175.

**G. The Continued-Availability Announcement in June 2014**

410. In the Summer of 2014, due to manufacturing issues with Namenda XR, Forest experienced a shortage in its Namenda XR supply.

Defendants' Evidence: Ex. 296, Declaration of Robert Stewart (Oct. 21, 2014), ¶ 10, FRX-AT-01771882; Ex. 365, Stewart (NYAG) Deposition, (Nov. 2, 2014) 49:25-67:25, 77:7-78:8, FRX-AT-01733121; Ex. 11, Meury (NYAG) Decl. at ¶¶ 22-23, FRX-AT-01771984.

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op., ¶¶ 98-99.

411. On June 10, 2014 Forest announced that it would not withdraw Namenda IR on August 15, 2014 as originally stated, due to the shortage.

Defendants' Evidence: Ex. 297, FRX-AT-01765949 (Press Release, Forest Labs, Forest Laboratories Announces Intention to Continue Marketing Both NAMENDA® TABLETS and Once-Daily NAMENDA XR® Into the Fall of 2014 (June 10, 2014)).

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count One, Dkt. 145, ¶ 85.

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op., ¶ 99.

412. Due to the temporary supply issues of Namenda XR, the conversion rate began to decline after July 2014, and likely caused many patients to switch from Namenda XR to Namenda IR during this time.

Defendants' Evidence: Ex. 198 Declaration of Jerry A. Hausman (Oct. 21, 2014), ¶ 14, FRX-AT-01779957.

## **H. The Standstill Agreement**

413. On February 28, 2014, the NYAG initiated an investigation into Forest's planned withdrawal of Namenda IR.

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op. at 5.

Plaintiffs' Admissions: DPPs' Mem. of Law ISO Count One, Dkt. 144 at 2.

414. The NYAG sought to prevent Forest from executing its business plan to "withdraw [Namenda IR] from the market" later that year, which the NYAG referred to as the "forced switch."

Undisputed Record Evidence: Ex. 298, Am. Complaint, *New York. v. Actavis, plc*, No. 1:14-cv-07473 (S.D.N.Y. Nov. 30, 2015), ¶ 2, FRX-AT-01747086.

415. On September 23, 2014, Forest agreed to a standstill of any future conduct.

Undisputed Record Evidence: Ex. 299, Letter to J. Sweet (Sept. 23, 2014), FRX-AT-01748060; Ex. 300, Letter to J. Sweet (Nov. 13, 2014), FRX-AT-01748115.

## **I. The December 2014 Injunction**

416. On December 15, 2014, Judge Sweet entered an injunction in the NYAG action. Pursuant to the injunction, Forest was required to continue to make Namenda IR tablets available on the same terms and conditions applicable since the date Namenda XR entered the market.

Undisputed Record Evidence: Ex. 288, December 2014 Injunction at 1.

Plaintiffs' Admissions: DPPs' Mem. of Law ISO Count One, Dkt. 144 at 2.

417. Forest was required to inform healthcare providers, pharmacists, patients, caregivers, and health plans of the injunction in the same or substantially similar manner in which Forest informed the market of Forest's plan to discontinue Namenda IR in February 2014.

Undisputed Record Evidence: Ex. 288, December 2014 Injunction at 1.

Defendants' Evidence: Ex. 290, Snyder Decl. ¶ 3.

418. "[T]he injunction protected competition and allowed low cost generic drugs to enter the market unimpeded . . . ."

Public Document: Press Release, New York Attorney General, A.G. Schneiderman Announcements Resolution of Lawsuit That Protected Alzheimer's Patients From Anticompetitive Tactic Aimed At Maintaining Higher Drug Prices (November 25, 2015).

419. The NYAG injunction required Forest to undo the effects of the February 2014 announcement.

Undisputed Record Evidence: Summary Judgment Mem. Decision and Order at 1, 16 (ECF No. 253) (indicating the NYAG injunction required Forest to "undo" the effects of the February 2014 announcement); Ex. 291, Settlement Agreement, *New York v. Actavis, plc*, No. 1:14-cv-07473 (S.D.N.Y. Nov. 30, 2015) (ECF No. 96-1) at 3 ("[T]he Injunction was effective in protecting competition in the relevant market . . . .").

420. "As a result of the injunction, Alzheimer's patients have not been forced to switch from Namenda IR to Namenda XR, and instead have been able to select which drug to use based on their and their physicians' views of which drug is best for them."

Public Document: Press Release, New York Attorney General, A.G. Schneiderman Announcements Resolution of Lawsuit That Protected Alzheimer's Patients From Anticompetitive Tactic Aimed At Maintaining Higher Drug Prices (November 25, 2015).

421. “Accordingly, as a result of the Attorney General’s lawsuit, patients who wished to remain on Namenda IR during early 2015 and then switch to the generic version when it became available over the summer were able to do so without any disruption in their medical treatment.”

Public Document: Press Release, New York Attorney General, A.G. Schneiderman Announcements Resolution of Lawsuit That Protected Alzheimer’s Patients From Anticompetitive Tactic Aimed At Maintaining Higher Drug Prices (November 25, 2015).

422. Forest complied with the NYAG injunction.

Defendants’ Evidence: Ex. 290, Snyder Decl. ¶¶ 3-6.

Undisputed Record Evidence: Ex. 291, Settlement Agreement, *New York. v. Actavis, plc*, No. 1:14-cv-07473 (S.D.N.Y. Nov. 30, 2015) (ECF No. 96-1) at 3 (indicating Forest complied with the injunction and informed constitutes of Namenda IR’s continued availability).

#### **J. The January 2015 Continued-Availability Announcement**

423. Forest was required to notify healthcare providers, pharmacists, patients, caregivers, and health plans of the injunction in the same or substantially similar manner as the February 2014 announcement.

Undisputed Record Evidence: Ex. 288, December 2014 Injunction.

Defendants’ Evidence: Ex. 290, Snyder Decl. ¶ 3.

424. Forest sent over 900,000 communications alerting the market of the injunction and continued availability of Namenda IR.

Defendants’ Evidence: Ex. 290, Snyder Decl. ¶¶ 3-6; Ex. 325, Snyder Dep. 115:3-19.

425. Forest compiled all of the communications sent as part of its February announcement in order to ensure that the same individuals and entities would also receive the announcement of the injunction and continued availability of Namenda IR.

Defendants' Evidence: Ex. 290, Snyder Decl. ¶ 4

426. Forest sent caregivers, health care providers, long term care facilities, and health plans over 900,000 communications alerting them of the injunction and the continued availability of Namenda IR.

Defendants' Evidence : Ex. 290, Snyder Decl. ¶ 5; Ex. 325, Snyder Dep. 114:20-11-115:19; Ex. 302, FRX-AT-03983934; Ex. 303, FRX-AT-04287221; Ex. 304, FRX-AT-04288492.

427. Forest updated its website for Namenda IR and Namenda XR to include a banner message which alerted the website visitor of the court order and continued availability of Namenda IR in a similar manner to the website announcements of the February 2014 withdrawal.

Defendants' Evidence: Ex. 290, Snyder Decl. ¶ 5

428. Forest issued a press release regarding the injunction, which was published in various websites, in a substantially similar form as the February 2014 announcement.

Defendants' Evidence: Ex. 290, Snyder Decl. ¶ 5

Public Document: December 11, 2014 Press Release from Actavis available at <https://www.allergan.com/investors/news/thomson-reuters/actavis-confirms-district-court-ruling-to-require>

429. Forest communicated with its sales representatives and managers about the continued availability of Namenda IR.

Defendant's Evidence: Ex. 325, Snyder Dep. 117-16-120:25; 139:13-25 (“Q. ... in the context here of making, of communicating with physicians about the injunction, do you know of any instances where sales representatives told physicians that Namenda Immediate release would not be discontinued after the injunction? A. Yes. There were definitely – sales representatives would have communicated that to physicians.”); Ex. 305, FRX-AT-03794674.

430. Forest's January 2015 announcements also mentioned the fact that Forest was appealing the December 2014 Injunction, no plan or even proposal to discontinue supply of Namenda IR was referenced together with the fact of Forest's appeal.

Defendants' Evidence: Ex. 290, Snyder Decl. ¶5; Ex. 325, Snyder Dep. 119:13-120:17; Ex. 302, FRX-AT-03983934; Ex 303, FRX-AT-04287221; Ex. 304, FRX-AT-04288492.

431. The New York Attorney General confirmed that Forest had performed its obligation to inform healthcare providers, pharmacists, patients, caregivers, and health plans of the December 2014 Injunction and the continued availability of Namenda IR “in the same or substantially similar manner in which it announced in February 2014 the potential plan to discontinue Namenda IR.”

Undisputed Record Evidence: Ex. 291, Settlement Agreement, *New York. v. Actavis, plc*, No. 1:14-cv-07473 (S.D.N.Y. Nov. 30, 2015) (ECF No. 96-1) at 3.

**K. Subsequent Announcements and the Settlement with the New York Attorney General**

432. On December 16, 2014, Forest filed a notice of appeal with the Second Circuit Court of Appeals.

Undisputed Record Evidence: Ex. 306, Notice of Appeal, *New York v. Actavis, plc*, No. 14-4624 (2d Cir. December 16, 2014) (ECF No. 1); Ex. 291, Settlement Agreement, *New York v. Actavis, plc*, No. 1:14-cv-07473 (S.D.N.Y. Nov. 30, 2015) (ECF No. 96-1) at 2.

433. On May 22, 2015, the Second Circuit affirmed the District Court's ruling and injunction.

Undisputed Record Evidence: Ex. 373, Order, *New York v. Actavis, plc*, No. 14-4624 (2d Cir. May 22, 2015) (ECF No. 336); Ex. 291, Settlement Agreement, *New York v. Actavis, plc*, No. 1:14-cv-07473 (S.D.N.Y. Nov. 30, 2015) (ECF No. 96-1) at 2.

434. Once Forest had lost its appeal, Forest circulated a press release stating the following and confirming that Namenda IR will remain on the market: "While we are disappointed by the Court's decision to uphold this ruling, we intend to continue our strong efforts to convey the significant benefits of NAMENDA XR® to physicians, patients and caregivers," said Brent Saunders, CEO and President of Actavis.

Defendants' Evidence: Ex. 307, FRX-AT-03671360.

Public Document: May 22, 2015 Press Release from Actavis available at <https://www.allergan.com/investors/news/thomson-reuters/actavis-confirms-appeals-court-ruling-requiring-co>

435. On November 4, 2015, Forest filed a petition for *certiorari* to the Supreme Court.

Undisputed Record Evidence: Ex. 291, Settlement Agreement, *New York v. Actavis, plc*, No. 1:14-cv-07473 (S.D.N.Y. Nov. 30, 2015) (ECF No. 96-1) at 2.

436. On November 30, 2015, with the petition for *certiorari* still pending, Forest and the NYAG entered into a settlement agreement.

Undisputed Record Evidence: Ex. 291, Settlement Agreement, *New York v. Actavis, plc*, No. 1:14-cv-07473 (S.D.N.Y. Nov. 30, 2015) (ECF No. 96-1) at 3 (indicating Forest

complied with the injunction and informed constitutes of Namenda IR's continued availability).

437. The NYAG and Forest agreed to dismiss, with prejudice, and release all claims, including those relating to damages, in connection with the NYAG action.

Undisputed Record Evidence: Ex. 291, Settlement Agreement, *New York. v. Actavis, plc*, No. 1:14-cv-07473 (S.D.N.Y. Nov. 30, 2015) (ECF No. 96-1) at 4-6.

**L. Entry of Generic Namenda IR in July and October of 2015**

438. The FDA approved ANDA 090048, Dr. Reddy's Laboratories Inc., U.S. ANDA for generic memantine on April 14, 2010.

Undisputed Evidence: Ex. 328, McCormick (DRL) Dep. 42:14-22.

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count Three, Dkt. 147, ¶ 42.

439. Dr. Reddy's launched generic memantine on July 11, 2015.

Undisputed Record Evidence: Ex. 328, McCormick (DRL) Dep. 54:24-55:2.

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count Three, Dkt. 147, ¶ 44.

440. The FDA approved ANDA 090058, Sun ANDA for generic memantine, on May 5, 2010.

Undisputed Record Evidence: Ex. 308, SUN0007329; Ex. 330, Nadkarni (Sun) Dep. 47:25-48:3.

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count Three, Dkt. 147, ¶ 97.

441. Sun launched generic memantine on July 11, 2015.

Undisputed Record Evidence: Ex. 330, Nadkarni (Sun) Dep. 64:18-66:14.

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count Three, Dkt. 147, ¶ 99.

442. The FDA approved ANDA 079225, Mylan's ANDA for generic memantine, on January 30, 2015.

Undisputed Record Evidence: Ex. 309, MYLMEMA\_000028.

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count Three, Dkt. 147, ¶ 70.

443. Mylan launched generic memantine on July 11, 2015.

Undisputed Record Evidence: Ex. 355, Curia (Mylan) Dep. 56:10-13.

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count Three, Dkt. 147, ¶ 72.

444. The FDA approved ANDA 090041, Amneal's ANDA for generic memantine, on April 10, 2015.

Undisputed Record Evidence: Ex. 327, Gupta (Amneal) Dep. 61:13-62:15; Ex. 310 Gupta Ex. 7.

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count Three, Dkt. 147, ¶ 28.

445. Amneal launched generic memantine on July 11, 2015.

Undisputed Record Evidence: Ex. 327, Gupta (Amneal) Dep. 68:21-25.

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count Three. Dkt. 147, ¶ 30.

446. The FDA approved ANDA 090051, Lupin's ANDA for generic memantine, on April 15, 2015.

Undisputed Record Evidence: Ex. 311, LPI-NMDA00004618.

447. Lupin launched generic memantine on July 13, 2015.

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count Three at 13 , Dkt. 147, ¶ 58.

448. The FDA approved ANDA 090073, Wockhardt's ANDA for generic memantine, on September 4, 2015.

Undisputed Record Evidence: Ex. 312, WOCKHARDT000000006; Ex. 351, Venkatesan (Wockhardt) Dep. 51:2-5.

449. Wockhardt launched generic memantine in November 2015.

Undisputed Record Evidence: Ex. 351, Venkatesan (Wockhardt) Dep. 72:15-18.

450. The FDA approved ANDA 200155, Torrent Pharma, Inc.'s ("Torrent") ANDA for generic memantine, on October 13, 2015.

Undisputed Record Evidence: Ex. 352, Gupta (Torrent) Dep. 20:24-21:3.

451. Torrent launched generic memantine on December 9, 2015, or soon thereafter.

Undisputed Record Evidence: Ex. 352, Gupta (Torrent) Dep. 30:9-31:3.

452. The FDA approved ANDA 090052, Teva's ANDA for generic memantine, on October 25, 2011.

Undisputed Record Evidence: Ex. 313, TEVANIR-00000459.

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count Three , Dkt. 147, ¶ 111.

453. Teva did not launch a generic memantine product under ANDA 090052.

Undisputed Record Evidence: Ex. 350, Cavanaugh (Teva) Dep. 72:25-73:11.

454. The FDA approved ANDA 090044, Orchid's ANDA for generic memantine, on March 12, 2012.

Undisputed Record Evidence: Ex. 204, ORGENUS0005365.

Plaintiffs' Admissions: DPPs' Statement of Material Facts ISO Count Three, Dkt. 147, ¶ 84.

455. Orchid did not launch a generic memantine product.

Undisputed Record Evidence: Ex. 334, Wilk (Orgenus) Dep. 160:9-161:13.

456. Apotex Inc. and Apotex Corp. (collectively "Apotex") filed ANDA 90-244 on January 11, 2008 and received tentative approval on May 1, 2012.

Undisputed Record Evidence: Ex. 205, Decl. of Kiran Krishnan (May 24, 2017), ¶¶ 2, 5.

457. Apotex has not yet obtained final FDA approval of ANDA 90-244 for generic memantine.

Undisputed Record Evidence: Ex. 205, Decl. of Kiran Krishnan (May 24, 2017), ¶ 5.

**M. No Way to Identify if Any Patients Switched Because of the February 2014 Announcement**

458. Plaintiffs have no evidence that any “certain patients” switched as a result of the February 2014 announcement.

Plaintiffs’ Admissions: Ex. 363, Lamb (Oct. 6, 2017) Dep. 54:2-13 (“Q. Sir with all due respect, we can discuss the appropriateness of the methodology but for the moment, all we’re trying to do is understand the methodology itself and how it works. So my next question is, **you testified that your model is not designed to understand specific patient behavior, I believe is the language you used.** Did I understand that correctly? A. You’d have to read back my exact words but I **think that’s a fair summary or characterization of my view on it, yes.**”) (emphasis added), 187:3-188:13 (describing such an analysis of patient decisions as “not the right analysis to do”); *see also* Ex. 349, Berndt Dep. 185:22-193:10 (“Q. And it’s fair to say you haven’t done any sort of regression or econometric model to look at other potential market events to deduce whether or not it was only favorable placement on Optum’s formulary and the announcement of the planned withdrawal that caused increased conversion in early 2014; is that fair? A. I have not undertaken any econometric analysis.”), 201:22-202:2 (“Q. ... Am I right you’ve done no quantitative assessment of the effect of the post-injunction real-world conversion rates in this case; is that right? A. That is correct.”).

459. Dr. Lamb, Plaintiffs’ Damages Expert, stated that his model is not based on “an analysis of an individual patient’s behavior” or “actual physician prescriptions.”

Plaintiffs’ Admissions: Ex. 363, Lamb (Oct. 6, 2017) Dep. 43:21-44:5 (“Q. Am I correct, sir, that the NSP database does not track actual physician prescriptions to compile its sales database? A. I believe that’s correct. I don’t believe that the NSP data is based on a survey or census of physician scripts, prescriptions. It’s based – pardon me, just to clarify my answer, it’s based on the movement of the product through the supply chain.”); *see also* Ex. 349, Berndt Dep. 168:17-170:3 (“But you don’t have any evidence here of a survey or otherwise of physicians and their habitual practices for prescribing Namenda XR and Namenda IR; correct? A. That is correct. I don’t have any specific evidence here. . . .”)

Defendants’ Evidence: Ex. 54, Fowdur Rep. ¶ 120 (explaining the role of patient behavior in physician decision making) (“Professor Berndt’s research also concludes in a different study that between 13% and 22% of prescription drug spending was attributable to the effects of direct-to-consumer advertising. Similarly, in another paper, Professor Berndt attests that 32% of patients who had seen advertising for a prescription drug in 2000 and 30% of patients in 2001 talked to their physician about the drug, and 13% of

patients indicated that their physician prescribed the drug that they asked about. Professor Berndt also found evidence that direct-to-consumer advertising was associated with increased initiation and appropriate duration of therapy.”).

460. Nor did Plaintiffs Damages Expert rely on data that “measures demand for prescription drugs including both what the provider prescribes in the retail setting and what is ultimately dispensed to consumers across four unique channels.”

Plaintiffs’ Admissions: Ex. 363, Lamb (Oct. 6, 2017) Dep. 187:3-188:13 (noting that analysis of physician prescriptions or patient switching is “not the right analysis to do”); *see also* Ex. 364, Lamb (Nov. 10, 2017) Dep. 16:6-19:18 (discussing Ex. 206, Lamb Ex. 11), 54:7-15 (Dr. Lamb conceded that he did not undertake any investigation or analysis of how many prescribing physicians had knowledge” of various financial calls or whether they impacted prescribing behavior”); *see also* Ex. 56, Lamb Reply Report ¶¶ 29, 79 (“an analysis of patient switching is irrelevant to the question of whether proposed Class members who are direct purchasers, not patients, were injured by Defendants’ challenged conduct.”), ¶¶ 85-87 (conceding that “physicians, not patients were a primary focus of Forest’s efforts”);

Public Documents: Ex. 206, IMS, “NPA Data Brief” at \*1 (“NPA is useful to address a variety of research topics examining pharmaceuticals, *especially investigations that focus on prescription drug utilization*, Rx size, average consumption, and more than 90 prescriber specialty groupings representing over 170 specialties.”) (emphasis added).

461. Instead, Plaintiffs Damages Expert conceded that his model relies on NSP data which monitors “the movement of the product through the supply chain.”

Plaintiffs’ Admissions: Ex. 363, Lamb (Oct. 6, 2017) Dep. 43:21-44:5.

462. Plaintiffs’ damages model is unable to discern changes in patient or prescriber behavior and cannot account for individual’s switching decisions.

Plaintiffs’ Admissions: Ex. 363, Lamb (Oct. 6, 2017) Dep. 56:7-21 (“Q: I think I understand your testimony. So in attempting in your methodology to assess the intended effect of the alleged hard switch at the market level, it’s possible that your damages calculation includes sales of XR to patients who simply prefer a once-a-day formulation. That’s possible. Correct? A. I think that’s possible. I have some – I think it’s possible.

I’m not sure what the relevance of it is for understanding how the product moved through the supply chain.”), 187:10-188:13 (explaining that his damages calculation is “not an analysis of patient scripts or patient behavior directly. That’s a – that’s not the right analysis to do.”).

463. Dr. Lamb stated that in his opinion, it was “not appropriate or necessary to look” at physician or patient preferences in this case or base an analysis of an “individual patient decision.”

Plaintiffs’ Admissions: Ex. 363, Lamb (Oct. 6, 2017) Dep. 51:20-56:5, 56:23-58:11.

**N. No Way to Know if Patients Switched to Namenda XR for Other Reasons, Including Lower Price, Formulary Placement, or Product Convenience**

464. Further, Plaintiffs have no evidence as to what portion of patients who converted to Namenda XR did so as a result of the announced withdrawal, as opposed to other reasons.

Plaintiffs’ Depositions: Ex. 349, Berndt Dep. 184:16-187:7 (conceding that the announcement was not the “sole cause” of patient switching); *see also* Ex. 363, Lamb (Oct. 6, 2017) Dep. 56:7-21 (“Q: I think I understand your testimony. So in attempting in your methodology to assess the intended effect of the alleged hard switch at the market level, it’s possible that your damages calculation includes sales of XR to patients who simply prefer a once-a-day formulation. That’s possible. Correct? A. I think that’s possible. I have some – I think it’s possible. I’m not sure what the relevance of it is for understanding how the product moved through the supply chain.”), 158:8-165:14 (distinguishing various conducts Forest undertook as part of its Namenda XR launch between “soft switch” tactics and conduct undertaken as part of a “hard switch strategy.”).

465. For example, doctors in the prior action testified that once-a-day dosing results in “greater compliance with treatment,” “improved tolerability . . . reduced total treatment costs, and better long-term clinical outcomes.”

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op. at ¶¶ 46-47.

466. Dr. Lamb's model is not able to identify any patients switched to Namenda XR because they preferred the once-a-day formulation of the drug.

Plaintiffs' Admissions: Ex. 363, Lamb (Oct. 6, 2017) Dep. 43:21-44:5 ("Q: Am I correct sir, that the NSP database does not track actual physician prescriptions to compile its sales database? A: I believe that's correct. I don't believe that the NSP data is based on a survey or census of physician scripts, prescriptions. It's based – pardon me, just to clarify my answer, it's based on the movement of the product through the supply chain."), 54:14-56:5; 56:23-58:11 ("Q: Similarly in your model that attempts to assess the intended effect of the alleged anticompetitive conduct at the market level, your model doesn't look at physician prescribing preferences. Correct? . . . A physician prescribing Namenda XR to a patient, for example, because of its once-a-day formulation? A: No, that's not appropriate or necessary to look at that issue. . . ."), 185:6-189:16. ("Q: There is no way we can tell from this data whether patients were reverse commuting to Namenda IR because of the supply shortage of Namenda XR. Correct? A: I think that's correct. . . ."); *see also* Ex. 349, Berndt Dep. 203:5-10 ("Q. And you don't do any quantitative analysis of whether patients actually switched from Namenda XR to generic Namenda IR in the real world after July 11, 2015, when generics entered; is that fair? A. That is correct.").

467. Dr. Lamb conceded that his model makes no effort to account for physician prescribing preferences and thus cannot discern whether prescribing patterns changed out of concern from the February 2014 announcement, or other decisions influencing physicians' prescribing behavior.

Plaintiffs' Admissions: Plaintiffs' Admissions: Ex. 363, Lamb (Oct. 6, 2017) Dep. 63:15-24 ("Q. We've established in your prior testimony that your model does not examine specific physician prescribing practices. Correct? A. That's correct, my model doesn't use physician prescribing practices. It's not appropriate or necessary to do so."); Ex. 364, Lamb (Nov. 10, 2017) Dep. 40:21-42:15 (discussing that Dr. Lamb did not conduct certain empirical analysis for physician prescribing preferences)..

468. Dr. Lamb stated that his structural break test "doesn't identify the cause of the break" which resulted in increased Namenda XR conversion in February 2014

Plaintiffs' Admissions: Ex. 363, Lamb (Oct. 6, 2017) Dep. 95:22-96:19; Ex. 364, Lamb (Nov. 10, 2017) Dep. 108:15-110:4 (Dr. Lamb conceded that his structural break analysis "[i]s not that finely honed that it could identify the first instance in which there was effect

on the market” from Forest’s conduct) *see also* Ex. 349, Berndt Dep. 183:16-187:7 (acknowledging that he did not perform econometric analyses to adduce which conduct drove which patient decision making).

469. Plaintiffs have not conducted any studies to as to consumer preferences regarding Namenda XR, or their decision to convert (i.e. whether the patient converted due to improved formulary placement, greater product awareness, or the February 2014 announcement).

Plaintiffs’ Admissions: Ex. 358, Benton (Smith Drug Co.) Dep. 142:13-16; Ex. 357, Doud (Rochester Drug Co.) Dep. 155:5-18.

470. Plaintiffs present no empirical evidence as to how physicians made their respective prescribing decisions.

Plaintiffs’ Admissions: Ex. 364, Lamb (Nov. 10, 2017) Dep. 40:21-43:14 (determining that all conclusions regarding whether physician behavior changed on the back of financial analysts calls were not based on “empirical analysis,” rather on a review of documentary evidence), 120:1-123:8 (Dr. Lamb testifying that he did not conduct any surveys or empirical analysis of physician’s perceived uncertainty about the memantine market or Namenda’s withdrawal); *see also* Ex. 349, Berndt Dep. 183:16-187:7 (acknowledging that he did not perform econometric analyses to adduce which conduct drove which patient decision making).

471. Based on NPA data, within one month of a generic entry, physicians continued to prescribe Namenda XR at a rate of over 60%, in comparison to prescriptions for Namenda IR.

Plaintiffs’ Admissions: Ex. 56, Lamb Reply Rep. ¶ 82 (“As a matter of economics, patients do not choose therapies. Doctors or physicians prescribe therapies which may or may not be covered by insurance plans.”).

Defendants’ Evidence: Ex. 54, Fowdur Rep. ¶¶ 101-102 (“Notably, in the last four weeks leading up to generic entry, a single month-long IR prescription would be sufficient to last until generic versions of IR were available. . . . Nevertheless, more than 60% of new patients picked Namenda XR over IR in that month. The high adoption rate of Namenda XR indicates that many patients had preferences for once-daily Namenda XR, did not have high switching costs, or both.”).

472. Throughout 2016, after generic entry and the court's injunction, physicians continued to prescribe Namenda XR to new patients at a rate of approximately 30-37%.

Defendants' Evidence: Ex. 54, Fowdur Rep. ¶ 141 (“[T]hroughout 2016, the weekly adoption rate of Namenda XR among new IR and XR patients averaged 32%. By 2016, generic IR had been on the market for many months, so new patients in 2016 could not conceivably have been influenced by the February 2014 announcement; rather, Forest only used competitively legitimate soft switch marketing and pricing to compete for these patients. Despite the significantly cheaper out-of-pocket cost for generic version of twice-a-day Namenda, almost one in every three new patients in 2016 revealed that they prefer Namenda XR to IR.”); *id.* at n. 320 (“Once-a-day versions of Namenda subsequent to June 2015 include Namenda XR and Namzaric. If I include Namzaric, the average once-a-day Namenda XR and Namzaric adoption rate for new patients in 2016 would be even higher at 37%”).

473. Namenda XR “is selling very well” almost over two full years after generic Namenda IR's entry.

Plaintiffs' Admissions: Ex. 357, Doud (Rochester Drug Co.) Dep. 155:9-18.

**O. No Way to Know How Many People Switched Back to Generic Namenda IR From Namenda XR**

474. Namenda XR and IR “are pharmacologically the same drug.”

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op., ¶ 109; Mem. and Order Denying Defendants' MTD, Dkt. 106, at 2.

475. Patients can safely transition between Namenda IR to Namenda XR without titration the next day.

Undisputed Record Evidence: Ex. 6, Unredacted Sweet Op., ¶ 53; Ex. 208, FRX-AT-01751482 (NYAG Nov. 13, 2014 Hr'g Tr.) 726:6-13 (Dr. Reisberg testifying “that there were no problems in switching patients back to the IR”), 742:13-22 (Dr. Kohrman stating that patients did not experience any side effects switching between Namenda XR and IR).

Defendants' Evidence: Ex. 197, FRX-AT-01765922 (Namenda XR Labeling Information)

476. The FDA concluded: “a patient who is stabilized with NAMENDA IR formulation 10 mg twice daily may directly switch to the XR formulation at a dose of 28 mg once daily with no additional titration or lag time.”

Public Documents: Ex. 319, FRX-AT-01769421 (FDA, *Center for Drug Evaluation and Research, Clinical Pharmacology and Biopharmaceutics Review of Namenda XR®*, at 4 (May 3, 2010)).

477. Generic Namenda IR entered the market in July 11, 2015.

Plaintiffs’ Admissions: DPPs’ Statement of Material Facts ISO Count Three, Dkt. 147, ¶¶ 28, 30, 42, 44, 58, 70, 72, 97, 99.

478. Plaintiffs have no evidence that patients did not switch between generic Namenda IR and Namenda XR, upon the entry of generic memantine into the market.

Plaintiffs’ Admissions: Ex. 349, Berndt Dep. 203:5-10 (“Q. And you don’t do any quantitative analysis of whether patients actually switched from Namenda XR to generic Namenda IR in the real world after July 11, 2015, when generics entered; is that fair? A. That is correct.”); *see also* Ex. 363, Lamb (Oct. 6, 2017) Dep. 188:15-189:16 (“[Q.] There is no way we can tell from this data [in Figure 7 of the Lamb report] whether patients were reverse commuting to Namenda IR because of the supply shortage of Namenda XR. Correct? A. I think that’s correct. This data discussed in Figure 7 isn’t analyzing patient behavior. . . . Forest didn’t think reverse commuting from XR to a generic version of IR was likely to happen when generic IR came on the marketplace. But this chart isn’t an analysis of that.”).

479. The NSP data relied on by DPP’s experts “provides data elements related to the sales dollars and volume of pharmaceutical products to retail and non-retail outlets” to track the supply pharmaceutical drugs, but does not track patient or physician demand for Namenda XR, Namenda IR, or generic memantine.

Plaintiffs’ Admissions: Ex. 56, Lamb Reply Rep. n. 77; Ex. 363, Lamb (Oct. 6, 2017) Dep. 43:21-44:5 (“Q: Am I correct sir, that the NSP database does not track actual physician prescriptions to compile its sales database? A: I believe that’s correct. I don’t

believe that the NSP data is based on a survey or census of physician scripts, prescriptions. It's based -- pardon me, just to clarify my answer, it's based on the movement of the product through the supply chain."), 185:6-189:16. ("Q: There is no way we can tell from this data whether patients were reverse commuting to Namenda IR because of the supply shortage of Namenda XR. Correct? A: I think that's correct. . . .").

Public Documents: Ex. 330, IMS, "HSRN DATA BRIEF: NATIONAL SALES PERSPECTIVES" at \*1-2.

480. From this supply data, Plaintiffs cannot offer empirical evidence as to the difficulties of reverse commuting.

Plaintiffs' Admissions: Ex. 363, Lamb (Oct. 6, 2017) Dep. 56:23-58:11 ("Q: Similarly in your model that attempts to assess the intended effect of the alleged anticompetitive conduct at the market level, your model doesn't look at physician prescribing preferences. Correct? . . . A physician prescribing Namenda XR to a patient, for example, because of its once-a-day formulation? A: No, that's not appropriate or necessary to look at that issue. . . ."), 188:15-189:16 ("[Q.] There is no way we can tell from this data [in Figure 7 of the Lamb report] whether patients were reverse commuting to Namenda IR because of the supply shortage of Namenda XR. Correct? A: I think that's correct. This data discussed in Figure 7 isn't analyzing patient behavior. . . . Forest didn't think reverse commuting from XR to a generic version of IR was likely to happen when generic IR came on the marketplace. But this chart isn't an analysis of that."); *see also* Ex. 364, Lamb (Nov. 10, 2017) Dep. 40:21-43:14 (determining that all conclusions regarding whether physician behavior changed on the back of financial analysts calls were not based on "empirical analysis," rather on a review of documentary evidence), 120:1-123:8 (Dr. Lamb testifying that he did not conduct any surveys or empirical analysis of physician's perceived uncertainty about the memantine market or Namenda's withdrawal); *see also* Ex. 349, Berndt Dep. 183:16-187:7 (acknowledging that he did not perform econometric analyses to adduce which conduct drove which patient decision making).

481. Documents Plaintiffs have relied upon do not provide evidence of how much reverse commuting was or was not occurring in the marketplace.

Defendants' Evidence: Ex. 195, FRX-AT-01606209 (June 2012 Forest email noting that "the key is not just conversion but also holding on to the XR business we get and not immediately losing it to generic IR. Managed care and LTC tells us that anyone converted [to Namenda XR] is likely to stay converted.").

482. Dr. Lamb does not cite empirical data to support his opinion that the cause of Namenda XR's gradual decline after generic entry was because patients did not or could not reverse commute.

Plaintiffs' Admissions: Ex. 193, Lamb Rep. I ¶ 109 (noting that the trend in DOT for Namenda XR in July 2015 "did not result in a sharp decline"); Ex. 363, Lamb (Oct. 6, 2017) Dep. 188:15-189:16 ("[Q.] There is no way we can tell from this data [in Figure 7 of the Lamb report] whether patients were reverse commuting to Namenda IR because of the supply shortage of Namenda XR. Correct? A. I think that's correct. This data discussed in Figure 7 isn't analyzing patient behavior. . . . Forest didn't think reverse commuting from XR to a generic version of IR was likely to happen when generic IR came on the marketplace. But this chart isn't an analysis of that.").

483. Plaintiffs have "done no quantitative assessment of the effect of the post-injunction real-world conversion rates in this case."

Plaintiffs Admissions: Ex. 349, Berndt Dep. 201:23-202:2; *see also* Ex. 364, Lamb (Nov. 10, 2017) Dep. 40:21-42:15 (discussing that Dr. Lamb did not conduct certain empirical analysis for physician behavior post-injunction).

**P. The Injunction Undid Any Purported Harm of the February 2014 Announcement**

484. On December 15, 2014, Judge Sweet entered an injunction in the NYAG action, requiring Forest to continue making Namenda IR tablets available and to alert healthcare providers, pharmacists, patients, caregivers, and health plans of the injunction in the same or substantially similar manner as the February 2014 announcement.

Defendants' Evidence: Ex. 288, FRX-AT-01747641 at 7641.

485. Forest complied with the injunction by compiling all of the communication sent as part of its February 2014 announcement and sent communications to the same list of individuals and entities in order to ensure that every individual who received notice of the

February 2014 announcement also received notice that Forest would maintain its supply of Namenda IR.

Defendants' Evidence: Ex. 290, Snyder Decl. ¶¶ 4-5; Ex. 81, FRX-AT-03670529 (Actavis press release providing news of the injunction)

Public Documents: Ex. 291, Settlement Agreement at 3, New York. v. Actavis, plc, No. 1:14-cv-07473 (S.D.N.Y. Nov. 30, 2015) (ECF No. 96-1) (indicating Forest complied with the injunction and informed constituents of Namenda IR's continued availability); Mem. Decision & Order at 1, 16, *In re Namenda Direct Purchaser Antitrust Litig.*, No. 15-cv-07488 (S.D.N.Y. May 23, 2017) (ECF No. 253) (describing the injunction as "requiring Forest to affirmatively undo the effects of its [February 2014] announcement of the withdrawal").

Defendants' Evidence: Ex. 325, Snyder Dep. 115:3-10, 139:13-25.

486. The Namenda XR adoption rate as of the injunction was not statistically different from the adoption rates that would have existed had no announcement been made.

Defendants' Evidence: Ex. 54, Fowdur Report ¶¶ 125-127, 131.

**Q. The January 2015 Continued-Availability Announcement Undid Any Purported Harm of the February 2014 Announcement**

487. Judge Sweet's injunction prevented Forest from halting sales of Namenda IR and required Forest to affirmatively undo the effects of the February 2014 announcement.

Undisputed Record Evidence: Mem. Decision & Order at 16 (May 23, 2017), ECF No. 253

Plaintiffs' Admissions: DPPs' Opp'n to Mot. to Dismiss at 38.

488. "[A]t the time of the injunction and Forest's public announcement that it had cancelled the planned withdrawal and would continue to supply Namenda IR, the level of adoption of Namenda XR in the actual world was consistent with the corresponding level in the but-for world."

Defendant's Evidence: Ex. 54, Fowdur Rep. ¶131.

489. Forest's effort to communicate that it would continue to sell Namenda IR in 2015 "mirrored the communications made in February 2014 announcing withdrawal."

Defendants' Evidence: Ex. 290, Snyder Decl. ¶¶ 4-5.

490. The efforts to communicate the Namenda IR withdrawal in February 2014 "was thwarted by the injunction entered in the New York Attorney General matter."

Plaintiffs' Admissions: Ex. 363, Lamb Dep. 35:1-22.

**R. The New York Attorney General Confirmed the Effect of the Announcement was Undone By Forest's Compliance with the Injunction**

491. At no time before, during or after the injunction was Namenda IR made unavailable or otherwise limited in distribution.

Undisputed Record Evidence: Ex. 291, NYAG Settlement Agreement, p. 3;

492. The injunction was effective in protecting the competition in the relevant market and permitting lower cost generic drugs to enter the market in July 2015 and subsequently.

Undisputed Record Evidence: Ex. 291, NYAG Settlement Agreement, p. 3;

493. "As a result of the injunction, Alzheimer's patients have not been forced to switch from Namenda IR to Namenda XR, and instead have been able to select which drug to use based on their and their physicians' views of which drug is best for them."

Statements from Publicly Available Sources: Nov. 25, 2015 Press Release: <https://ag.ny.gov/press-release/ag-schneiderman-announces-resolution-lawsuit-protectedalzheimere2%80%99s-patients>

494. “Patients who wished to remain on Namenda IR during early 2015 and then switch to the generic version when it became available over the summer were able to do so without any disruption in their medical treatment. In addition, Alzheimer’s patients who wish to take Namenda XR instead of Namenda IR are also free to do so.”

Statements from Publicly Available Sources: Nov. 25, 2015 Press Release: <https://ag.ny.gov/press-release/ag-schneiderman-announces-resolution-lawsuit-protected-alzheimer%E2%80%99s-patients>.

Dated: December 6, 2017

**WHITE & CASE LLP**

By: 

Heather K. McDevitt

Martin M. Toto

John H. Chung

Ryan P. Johnson

William H. Bave, III

Michael E. Hamburger

Kristen O'Shaughnessy

WHITE & CASE LLP

1221 Avenue of the Americas

New York, New York 10020

Telephone: (212) 819-8200

J. Mark Gidley

Peter J. Carney

WHITE & CASE LLP

701 Thirteenth Street, NW

Washington, DC 20005

Telephone: (202) 626-3600

Heather M. Burke  
WHITE & CASE LLP  
3000 El Camino Real  
5 Palo Alto Square, 9th Floor  
Palo Alto, CA 94306  
Telephone: (650) 213-0300

Kevin C. Adam  
WHITE & CASE LLP  
75 State Street, Floor 24  
Boston, MA 02109  
Telephone: (617) 979-9300

**Counsel for Defendants Actavis plc,  
Forest Laboratories, LLC, Forest  
Laboratories, Inc., and Forest  
Laboratories Holdings Ltd.**